

US3912121 (Prod: Synexus - Optimal Research - Austin)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:17:58

All time stamps listed in this document are displayed in GMT

US3912121

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 16:23:40

Generated On: 10 Jun 2021 10:17:58

Participant ID

US3912121

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

US3912121

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Date of Informed Consent (<i>dd MMM yyyy</i>)	08 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) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	BELL'S PALSY
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	TOTAL ABDOMINAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1972
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 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	SULFA ALLERGY-HIVES
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	DEMEROL ALLERGY-VOMITING
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	ZOFRAN ALLERGY-VOMITING
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	THYROIDECTOMY
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	BENIGN THYROID NODULES
Start date (dd MMM yyyy)	UN UNK 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	GALLBLADDER REMOVAL
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 (12)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	HEART ABLATION
Start date (dd MMM yyyy)	UN MAY 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 MAY 2012
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2012
Start Year (derived)	2012
Stop Month and Year (derived)	MAY 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	ARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	LEFT KNEE REPLACEMENT (SECONDARY TO ARTHRITIS)
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	LEFT HIP REPLACEMENT (SECONDARY TO ARTHRITIS)
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	RIGHT SHOULDER REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	FALL-SHOULDER INJURY (RIGHT)
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	GALL STONES
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3912121

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

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

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	CATARACTS-BILATERAL
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAY 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	DIRECT CURRENT CARDIOVERSION (1ST IN FEB 2012; 2ND MAY 2012)
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) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	DECREASED RANGE OF MOTION RIGHT HIP
Start date (dd MMM yyyy)	08 SEP 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

Condition	HYPOTHYROIDISM (POST-SURGICAL)
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 28 Mar 2021 16:23:09

Generated On: 10 Jun 2021 10:17:58

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:30 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:30
Height (<i>xxx.x</i>)	64.0 in
Weight (<i>xxx.x</i>)	155.0 lb
BMI (<i>xxx.x</i>)	26.66132 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) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 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) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Date of assessment (dd MMM yyyy) 08 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 UNK 1984

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) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

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 > 65 YRS OF AGE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:23:42

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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)	False
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) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 190047

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

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)	08 SEP 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:30
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	14:11 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 14:11
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3912121

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

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.

US3912121

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 12:54 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 12:54

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

US3912121

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 SEP 2020
Collection time (00:00-23:59)	12:12 (24 HR)
Collection date and time (derived)	08 SEP 2020 12:12

US3912121

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:17	08 SEP 2020 12:17
Nasopharyngeal Swab 2	No		

US3912121

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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 14:15

PC Open Date & Time

08 SEP 2020 13:14

PC Close Date & Time

08 SEP 2020 15:44

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °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	08 SEP 2020 20:54
PC Open Date & Time	08 SEP 2020 16:39
PC Close Date & Time	09 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

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

96.3 °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 21:04

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 19:18

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 19:04

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

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

96.7 °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

12 SEP 2020 18:34

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 19:57

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

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

98.1 °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

15 SEP 2020 00:51

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 14:16

PC Open Date & Time

08 SEP 2020 13:14

PC Close Date & Time

08 SEP 2020 15:44

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

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

08 SEP 2020 20:55

PC Open Date & Time

08 SEP 2020 16:39

PC Close Date & Time

09 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

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

09 SEP 2020 21:04

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

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

10 SEP 2020 19:18

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

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

11 SEP 2020 19:06

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

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

12 SEP 2020 18:34

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

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

13 SEP 2020 19:58

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

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

15 SEP 2020 00:51

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

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 ☐

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 14:17
PC Open Date & Time	08 SEP 2020 13:14
PC Close Date & Time	08 SEP 2020 15:44

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

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 ☐

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 20:56
PC Open Date & Time	08 SEP 2020 16:39
PC Close Date & Time	09 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

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)

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 21:05
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

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)

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 18:35
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:58
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

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)

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 00:51
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3912121

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912121

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912121

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912121

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

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)	06 OCT 2020
Time of assessment (00:00-23:59)	09:16 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 09:16
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 11:50
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3912121

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3912121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

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) 06 OCT 2020

What was the treatment time? (00:00-23:59) 10:55 (24 HR)

Treatment Date and Time (derived) 06 OCT 2020 10:55

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

US3912121

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 OCT 2020
Collection time (00:00-23:59)	10:09 (24 HR)
Collection date and time (derived)	06 OCT 2020 10:09

US3912121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Collection date (dd MMM yyyy)			06 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:18	06 OCT 2020 10:18
Nasopharyngeal Swab 2	No		

US3912121

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 11:52

PC Open Date & Time

06 OCT 2020 11:15

PC Close Date & Time

06 OCT 2020 13:45

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °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 OCT 2020 20:21
PC Open Date & Time	06 OCT 2020 14:40
PC Close Date & Time	07 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

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

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

07 OCT 2020 21:07

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 20:12

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 21:17

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 20:24

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 21:12

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 21:09

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

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

06 OCT 2020 11:53

PC Open Date & Time

06 OCT 2020 11:15

PC Close Date & Time

06 OCT 2020 13:45

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

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

06 OCT 2020 20:22

PC Open Date & Time

06 OCT 2020 14:40

PC Close Date & Time

07 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

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

07 OCT 2020 21:07

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

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

08 OCT 2020 20:13

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

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

09 OCT 2020 21:18

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

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

10 OCT 2020 20:25

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

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

11 OCT 2020 21:12

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

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

12 OCT 2020 21:10

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

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 ☐

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 11:54
PC Open Date & Time	06 OCT 2020 11:15
PC Close Date & Time	06 OCT 2020 13:45

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

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 ☐

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 20:22
PC Open Date & Time	06 OCT 2020 14:40
PC Close Date & Time	07 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

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 ☒

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 21:08
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

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)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 20:14
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

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 ☒

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 21:19
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 20:25
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 21:13
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 21:11
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3912121

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912121

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912121

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912121

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 NOV 2020
Time of assessment (00:00-23:59)	09:19 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 09:19
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912121

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

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.

US3912121

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 NOV 2020

Collection time (00:00-23:59)

09:35 (24 HR)

Collection date and time (derived)

03 NOV 2020 09:35

US3912121

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:23:42

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 17:22:01

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 17:58:01

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 19:50:19

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 18:54:39

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 DEC 2020 18:26:48
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
Nausea	True
Vomiting	True
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	18 DEC 2020 03:50:39
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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 <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"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	04 JAN 2021 21:31:21
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

11 JAN 2021 20:12:52

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

18 JAN 2021 21:55:41

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

25 JAN 2021 21:04:15

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

08 FEB 2021 22:37:36

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 19:38:35
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 18:55:40

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 12:52:10

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 18:38:50

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 18:31:48

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

29 MAR 2021 20:22:49

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 12:10:37

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 18:00:06

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 16:07:38

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 20:34:13

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 17:58:07

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 250

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 257

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

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

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

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

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

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

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 ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 355

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 467

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

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

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

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

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 481

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

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

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

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

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 516

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

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

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

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

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

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

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 ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 537

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

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

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

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

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

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

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 ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	12 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 628

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

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

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

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

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

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

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 ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 684

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	18 AUG 2022 00:01
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Patient Cloud Close Date & Time	22 AUG 2022 23:59
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US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	01 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 761

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

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

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

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

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

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

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	10 NOV 2022 00:01
Patient Cloud Close Date & Time	14 NOV 2022 23:59

US3912121

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:17:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 18:56:08

US3912121

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3912121

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912121

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912121

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912121

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 17:52:14

Generated On: 10 Jun 2021 10:17:58

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

Visit date (dd MMM yyyy)	30 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 17:52:14

Generated On: 10 Jun 2021 10:17:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	09:28 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 09:28
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	172 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912121

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 17:52:14

Generated On: 10 Jun 2021 10:17:58

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.

US3912121

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 17:52:14

Generated On: 10 Jun 2021 10:17:58

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

Collection date (dd MMM yyyy)	30 MAR 2021
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Collection time (00:00-23:59)	09:59 (24 HR)
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Collection date and time (derived)	30 MAR 2021 09:59
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US3912121

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 17:52:14

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3912121

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:17:58

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3912121

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

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

Visit date (dd MMM yyyy)	12 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3912121

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 19:11:42

Generated On: 10 Jun 2021 10:17:58

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	12 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3912121

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Height	
Weight	
BMI (xxx.x)	

US3912121

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 FEB 2021
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 12:40
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3912121

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 FEB 2021
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 14:35
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3912121

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

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 FEB 2021

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

US3912121

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

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 8 FEB 2021

What was the treatment time? (00:00-23:59) 13:52 (24 HR)

Treatment Date and Time (derived) 8 FEB 2021 13:52

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

What was the frequency of the study treatment dosing? ONCE

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

US3912121

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	13:47 (24 HR)
Collection date and time (derived)	12 JAN 2021 13:47

US3912121

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

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

Collection date (dd MMM yyyy)	12 JAN 2021
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Collection time (00:00 - 23:59)	13:51
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Collection Date and Time (derived)	12 JAN 2021 13:51
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US3912121

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912121

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

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)	5 MAR 2021
Time of assessment (00:00-23:59)	13:32 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 13:32
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 MAR 2021
Time of assessment (00:00-23:59)	15:42 (24 HR)
Vital Signs Date and Time (derived)	5 MAR 2021 15:42
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3912121

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 MAR 2021

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

US3912121

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 5 MAR 2021

What was the treatment time? (00:00-23:59) 14:57 (24 HR)

Treatment Date and Time (derived) 5 MAR 2021 14:57

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

US3912121

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 21:17:02

Generated On: 10 Jun 2021 10:17:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3912121

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 21:17:02

Generated On: 10 Jun 2021 10:17:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3912121

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 17:52:14

Generated On: 10 Jun 2021 10:17:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 17:52:14

Generated On: 10 Jun 2021 10:17:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	09:28 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 09:28
Temperature (<i>xxx.x</i>)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	56 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	172 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3912121

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 17:52:14

Generated On: 10 Jun 2021 10:17:58

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.

US3912121

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 17:52:14

Generated On: 10 Jun 2021 10:17:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	09:59 (24 HR)
Collection date and time (derived)	30 MAR 2021 09:59

US3912121

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3912121

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Mar 2021 19:56:41

Generated On: 10 Jun 2021 10:17:58

AEID	USA-US211-2020-MRNA-1273-P30 1000009
Adverse event	SMALL BOWEL OBSTRUCTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	18 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	28 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Mar 2021 19:56:41

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Mar 2021 19:56:41

Generated On: 10 Jun 2021 10:17:58

THE SUBJECT INITIALLY PRESENTED TO THE ER WITH ABDOMINAL PAIN STARTING THE DAY PRIOR; THE PAIN IS DESCRIBED AS SHARP, ACHY LOWER ABDOMINAL PAIN WITHOUT RADIATION WITH ASSOCIATED INTRACTABLE NAUSEA AND VOMITING. UPON EXAMINATION THERE WAS ABDOMINAL DISTENTION NOTED WITH TENDERNESS AND SILENT BOWEL SOUNDS. SHE WAS IMMEDIATELY SENT FOR CT OF ABDOMEN AND PELVIS WHICH REVEALED CLOSED LOOP SMALL BOWEL OBSTRUCTION FOR WHICH SHE WAS SCHEDULED FOR EMERGENT SURGERY. THE INITIAL RECOMMENDATION FROM CONSULTATION WAS TO UNDERGO URGENT DIAGNOSTIC LAPAROSCOPY WITH POSSIBLE LAPAROTOMY; HOWEVER IN THE OR THE EXPLORATORY LAPAROSCOPY CONVERTED TO OPEN BOWEL RESECTION. NOTE: SUBJECT HAD NEGATIVE COVID TEST ON ADMISSION 18DEC2020.

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

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Mar 2021 19:56:41

Generated On: 10 Jun 2021 10:17:58

AEID	USA-US211-2020-MRNA-1273-P30 1000009
Adverse event	PAROXYSMAL ATRIAL FIBRILLATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	20 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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)	18 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	28 DEC 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Mar 2021 19:56:41

Generated On: 10 Jun 2021 10:17:58

Number of Days in ICU	10
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	

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 09 Mar 2021 19:56:41

Generated On: 10 Jun 2021 10:17:58

73 YEAR OLD WITH HISTORY
OF PAF S/P MULTIPLE
CARDIOVERSIONS AND
ABLATION IN 2012. POST
SURGERY HEART RATE IN
120-130S, STABLE BLOOD
PRESSURE. ON TTE
PERFORMED 21DEC2020,
FINDINGS REVEALED
PRESERVED LVEF WITH
DILATED ATRIA, NO
SIGNIFICANT VALVULAR
ABNORMALITIES BUT WITH
ELEVATED FILLING PRESSURES
AND DILATED IVC,
CONSISTENT WITH
HYPERVOLEMIA; SHE WAS
STARTED ON DILTIAZEM AND
HAD UNCONTROLLED RATES,
THEN GIVEN DIGOXIN WITH NO
IMPROVEMENT.
SUBSEQUENTLY GIVEN
AMIODARONE LOADED AND
STARTED ON ESMOLOL.

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

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Mar 2021 19:56:41

Generated On: 10 Jun 2021 10:17:58

AEID	
Adverse event	LEFT ATRIUM DILATION
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Mar 2021 19:56:41

Generated On: 10 Jun 2021 10:17:58

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

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 09 Mar 2021 19:56:41

Generated On: 10 Jun 2021 10:17:58

DURING THE
HOSPITALIZATION OF THIS
SUBJECT, SHE WAS
EVALUATED FOR POSSIBLE
POST-OP STROKE. A
TRANSTHORACIC
ECHOCARDIOGRAM WAS
PERFORMED ON 21DEC2020
WHICH REVEALED FINDINGS
OF 'SEVERELY DILATED LEFT
ATRIUM'.

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)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Mar 2021 19:56:41

Generated On: 10 Jun 2021 10:17:58

AEID

Adverse event

RIGHT PLEURAL EFFUSION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Mar 2021 19:56:41

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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	THIS FINDING WAS DOCUMENTED ON THE CT PERFORMED ON 18DEC2020; THERE DOES NOT APPEAR TO BE ANY FOLLOW UP OTHERWISE DURING THE HOSPITALIZATION.,
Serious Adverse Event Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 09 Mar 2021 19:56:41

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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) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

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) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication SOTALOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	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 (2)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 1984
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 (3)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication ELOQUIST

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="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 (4)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication PREMARIN

Prophylaxis Yes ☐
No ☒

Indication HORMONE REPLACEMENT

Dose per administration .9

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input 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 1984
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) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 15:47:13

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 15:47:13

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Name of Medication TYLENOL ARTHRITIS

Prophylaxis Yes ☐
No ☒

Indication ARTHRITIS

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 (6)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input 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 (7)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 1

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

If dose unit is Other, specify INJECTION

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
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) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	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)		21 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication PHENERGAN

Prophylaxis Yes ☐
No ☒

Indication SMALL BOWL OBSTRUCTION

Dose per administration 6.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication SMALL BOWEL OBSTRUCTION

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 (9)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication CEFEPIME

Prophylaxis Yes ☒
No ☐

Indication INFECTION PROPHYLAXIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication PAROXYSMAL A-FIB

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication DILTIAZEM

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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US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERKALEMIA

Dose per administration 20

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

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) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication DIGOXIN

Prophylaxis Yes ☐
No ☒

Indication PAROXYSMAL A-FIB

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 (15)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication TRAZODONE

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 (17)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication LOVENOX

Prophylaxis Yes ☒
No ☐

Indication CLOT PREVENTION

Dose per administration 70

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication ZYPREXA

Prophylaxis Yes ☐
No ☒

Indication POST-OP ALTERED MENTAL STATUS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication SMALL BOWEL OBSTRUCTION

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 (20)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	24 DEC 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM POST
THYROIDECTOMY

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POST SURGERY - SMALL
BOWEL OBSTRUCTION

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 06 Apr 2021 15:47:13

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Name of Medication ESMOLOL

Prophylaxis Yes ☐
No ☒

Indication PAROXYSMAL A-FIB

Dose per administration 2500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication TPN ADULT
(AMINO ACID/DEXTROSE
SOLUTION AND A LIPID
EMULSION)

Prophylaxis Yes ☐
No ☒

Indication NUTRITIONAL SUPPORT

Dose per administration 1680

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Transdermal	<input type="checkbox"/>
Intraocular	<input type="checkbox"/>
Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	21 DEC 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

If not Ongoing, End date (dd MMM yyyy)	28 DEC 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication PAROXYSMAL A-FIB

Dose per administration 450

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	27 DEC 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication PAROXYSMAL A-FIB

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 DEC 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 (27)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication CEFEPIME

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR SMALL
BOWEL OBSTRUCTION

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication DIGOXIN

Prophylaxis Yes ☐
No ☒

Indication PAROXYSMAL A-FIB

Dose per administration 0.125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication SOTOLOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 06 Apr 2021 15:47:13

Generated On: 10 Jun 2021 10:17:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 16:23:41

Generated On: 10 Jun 2021 10:17:58

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 DEC 2020	BOWEL RESECTION	Adverse Event	
18 DEC 2020	CT ABDOMEN/PELVIS WITH CONTRAST	Diagnostic	
18 DEC 2020	X-RAY CHEST	Diagnostic	
18 DEC 2020	ELECTROCARDIOGRAM	Diagnostic	
21 DEC 2020	TRANSTHORACIC ECHOCARDIOGRAM	Diagnostic	

US3912121

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:17:58

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

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Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

SAEID	USA-US211-2020-MRNA-1273-P301000009
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	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

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Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

SAEID	USA-US211-2020-MRNA-1273-P301000009
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	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/DEC/2020 09:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

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Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

SAEID	USA-US211-2020-MRNA-1273-P301000009
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	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/DEC/2020 10:37
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

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

SAEID	USA-US211-2020-MRNA-1273-P301000009
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	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/DEC/2020 14:14
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

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

SAEID	USA-US211-2020-MRNA-1273-P301000009
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	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	05/JAN/2021 15:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

SAEID	USA-US211-2020-MRNA-1273-P301000009
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	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/JAN/2021 16:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

SAEID	USA-US211-2020-MRNA-1273-P301000009
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	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/JAN/2021 10:39
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

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Data signed: (b) (4) 09 Mar 2021 19:56:42

Generated On: 10 Jun 2021 10:17:58

SAEID	USA-US211-2020-MRNA-1273-P301000009
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	MARK
Investigator's Last Name	HUTCHENS
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/FEB/2021 13:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3912121 (Prod: Synexus - Optimal Research - Austin)

US3912121

Form: Participant Creation

Generated On: 10 Jun 2021 10:17:58

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'US3912121'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:04:58

US3912121

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Tina Rountree (b) (4)	08 Sep 2020 16:50:23

US3912121

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:04:59

US3912121

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Clinic (Clinic)'	Tina Rountree (b) (4)	08 Sep 2020 16:50:23

US3912121

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'SCRN'	System	08 Sep 2020 16:50:23

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:05:00

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '73'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:11

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'YEARS'	System	08 Sep 2020 19:03:11

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '73'	System	08 Sep 2020 19:03:25

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:11

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:11

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:11

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:11

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:11

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:11

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:11

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:11

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:11

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:11

US3912121

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:17:58

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:11

US3912121

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:25

US3912121

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Sep 2020'	System	08 Sep 2020 19:03:25

US3912121

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2020'	System	08 Sep 2020 19:03:25

US3912121

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:58

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:25

US3912121

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:25

US3912121

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:25

US3912121

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:25

US3912121

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:58

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:25

US3912121

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 15:04:59

US3912121

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:17:58

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'I'	System	08 Sep 2020 19:03:31

US3912121

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:31

US3912121

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:17:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 16:29:06

US3912121

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	17 Sep 2020 13:23:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 13:23:39
Data point term sent to Coder	System	10 Sep 2020 16:32:50
User entered 'PREDNISONE ALLERGY-RASH'	Amy Collins (b) (4) (b) (4)	10 Sep 2020 16:31:51

US3912121

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2018'	Amy Collins (b) (4)	10 Sep 2020 16:31:51

US3912121

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 16:31:51

US3912121

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 16:31:51

US3912121

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 16:31:51

US3912121

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 16:31:51

US3912121

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2018'	System	10 Sep 2020 16:31:51

US3912121

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2018'	System	10 Sep 2020 16:31:51

US3912121

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 16:31:51

US3912121

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 16:31:51

US3912121

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Nervous system disorders, HLGT: Cranial nerve disorders (excl neoplasms), HLT: Facial cranial nerve disorders, PT: Facial paralysis, LLT: Bell's palsy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Sep 2020 16:43:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:43:41
Data point term sent to Coder	System	10 Sep 2020 16:43:09
User entered 'BELL'S PALSY'	Amy Collins (b) (4) (b) (4)	10 Sep 2020 16:42:28

US3912121

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2018'	Amy Collins (b) (4)	10 Sep 2020 16:42:28

US3912121

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 16:42:28

US3912121

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 16:42:28

US3912121

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2019'	Amy Collins (b) (4)	10 Sep 2020 16:42:28

US3912121

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 16:42:28

US3912121

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2018'	System	10 Sep 2020 16:42:28

US3912121

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2018'	System	10 Sep 2020 16:42:28

US3912121

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2019'	System	10 Sep 2020 16:42:28

US3912121

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2019'	System	10 Sep 2020 16:42:28

US3912121

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total abdominal hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:44:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 16:44:44
Data point term sent to Coder	System	10 Sep 2020 16:44:10
User entered 'TOTAL ABDOMINAL HYSTERECTOMY'	Amy Collins (b) (4)	10 Sep 2020 16:43:16

US3912121

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1984'	Amy Collins (b) (4)	10 Sep 2020 16:43:16

US3912121

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 16:43:16

US3912121

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 05:37:31
' (Site from DM).		
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:53:47
' answered with 'Data corrected' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	12 Oct 2020 19:53:40
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate.	(b) (4), (b) (6)	12 Oct 2020 18:50:45
' (Site from DM).		
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	10 Sep 2020 16:43:16

US3912121

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'un UNK 1984' reason for change:	(b) (4)	
Data Entry Error	Mia Rountree (b) (4)	12 Oct 2020 19:53:40
User entered empty.	(b) (4)	
	Amy Collins (b) (4)	10 Sep 2020 16:43:16
	(b) (4)	

US3912121

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 16:43:16

US3912121

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1984'	System	10 Sep 2020 16:43:16

US3912121

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1984'	System	10 Sep 2020 16:43:16

US3912121

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1984'	System	12 Oct 2020 19:53:40
User entered empty.	System	10 Sep 2020 16:43:16

US3912121

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1984'	System	12 Oct 2020 19:53:40
User entered empty.	System	10 Sep 2020 16:43:16

US3912121

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:03:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:03:46
Data point term sent to Coder	System	10 Sep 2020 17:03:13
User entered 'ENDOMETRIOSIS'	Amy Collins (b) (4)	10 Sep 2020 17:02:31

US3912121

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1972'	Amy Collins (b) (4)	10 Sep 2020 17:02:31

US3912121

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:02:31

US3912121

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 17:02:31

US3912121

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1984'	Amy Collins (b) (4)	10 Sep 2020 17:02:31

US3912121

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:02:31

US3912121

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1972'	System	10 Sep 2020 17:02:31

US3912121

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1972'	System	10 Sep 2020 17:02:31

US3912121

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1984'	System	10 Sep 2020 17:02:31

US3912121

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1984'	System	10 Sep 2020 17:02:31

US3912121

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:03:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:03:45
Data point term sent to Coder	System	10 Sep 2020 17:03:14
User entered 'SULFA ALLERGY-HIVES'	Amy Collins (b) (4)	10 Sep 2020 17:03:02

US3912121

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1984'	Amy Collins (b) (4)	10 Sep 2020 17:03:02

US3912121

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:03:02

US3912121

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 17:03:02

US3912121

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 17:03:02

US3912121

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:03:02

US3912121

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1984'	System	10 Sep 2020 17:03:02

US3912121

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1984'	System	10 Sep 2020 17:03:02

US3912121

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:03:02

US3912121

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:03:02

US3912121

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Oct 2020 15:55:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 15:55:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 23:08:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 23:08:46
Data point term sent to Coder	System	10 Sep 2020 17:11:42
User entered 'DEMEROL ALLERGY-VOMITING'	Amy Collins (b) (4) (b) (4)	10 Sep 2020 17:11:40

US3912121

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1995'	Amy Collins (b) (4)	10 Sep 2020 17:11:40

US3912121

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:11:40

US3912121

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 17:11:40

US3912121

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 17:11:40

US3912121

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:11:40

US3912121

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1995'	System	10 Sep 2020 17:11:40

US3912121

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1995'	System	10 Sep 2020 17:11:40

US3912121

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:11:40

US3912121

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:11:40

US3912121

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 12:30:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	13 Sep 2020 12:30:50
Data point term sent to Coder	System	10 Sep 2020 17:12:42
User entered 'ZOFRAN ALLERGY-VOMITING'	Amy Collins (b) (4)	10 Sep 2020 17:12:15

US3912121

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2014'	Amy Collins (b) (4)	10 Sep 2020 17:12:15

US3912121

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:12:15

US3912121

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 17:12:15

US3912121

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 17:12:15

US3912121

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:12:15

US3912121

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2014'	System	10 Sep 2020 17:12:15

US3912121

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2014'	System	10 Sep 2020 17:12:15

US3912121

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:12:15

US3912121

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:12:15

US3912121

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Per MM: Please consider recoding to SOC: Immune system disorders HLGT: Allergic conditions HLT: Allergies to foods, food additives, drugs and other chemicals PT: Drug hypersensitivity LLT: Penicillin allergy. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 11:34:54
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:03:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:03:40
Query 'Per MM: Please consider recoding to SOC: Immune system disorders HLGT: Allergic conditions HLT: Allergies to foods, food additives, drugs and other chemicals PT: Drug hypersensitivity LLT: Penicillin allergy. ' answered with 'updated condition' (Site from DM).	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:02:47
Data point term sent to Coder	System	03 Oct 2020 15:02:31
Coding entries removed.	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:02:30
User entered 'PENICILLIN ALLERGY' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:02:30
User opened query 'Per MM: Please consider recoding to SOC: Immune system disorders HLGT: Allergic conditions HLT: Allergies to foods, food additives, drugs and other chemicals PT: Drug hypersensitivity LLT: Penicillin allergy. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 07:50:08

US3912121

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:58

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 12:24:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 12:24:36
Data point term sent to Coder	System	10 Sep 2020 17:13:43
User entered 'PENICILLIN ALLERGY-RASH'	Amy Collins (b) (4)	10 Sep 2020 17:12:55

US3912121

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1990'	Amy Collins (b) (4)	10 Sep 2020 17:12:55

US3912121

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:12:55

US3912121

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 17:12:55

US3912121

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 17:12:55

US3912121

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:12:55

US3912121

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1990'	System	10 Sep 2020 17:12:55

US3912121

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1990'	System	10 Sep 2020 17:12:55

US3912121

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:12:55

US3912121

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:12:55

US3912121

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:14:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:14:49
Data point term sent to Coder	System	10 Sep 2020 17:13:46
User entered 'THYROIDECTOMY'	Amy Collins (b) (4)	10 Sep 2020 17:13:41

US3912121

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1984'	Amy Collins (b) (4)	10 Sep 2020 17:13:41

US3912121

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:13:41

US3912121

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 17:13:41

US3912121

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1984'	Amy Collins (b) (4)	10 Sep 2020 17:13:41

US3912121

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:13:41

US3912121

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1984'	System	10 Sep 2020 17:13:41

US3912121

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1984'	System	10 Sep 2020 17:13:41

US3912121

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1984'	System	10 Sep 2020 17:13:41

US3912121

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1984'	System	10 Sep 2020 17:13:41

US3912121

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms benign, HLT: Thyroid neoplasms benign, PT: Benign neoplasm of thyroid gland, LLT: Benign thyroid nodule - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	10 Sep 2020 17:16:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:16:45
Data point term sent to Coder	System	10 Sep 2020 17:15:55
User entered 'BENIGN THYROID NODULES'	Amy Collins (b) (4)	10 Sep 2020 17:15:32

US3912121

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1982'	Amy Collins (b) (4)	10 Sep 2020 17:15:32

US3912121

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:15:32

US3912121

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	10 Sep 2020 17:15:56
User entered 'No (N)' reason for change: Data Entry Error	Amy Collins (b) (4) (b) (4)	10 Sep 2020 17:15:56
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	10 Sep 2020 17:15:32
User entered 'Yes (Y)'	Amy Collins (b) (4) (b) (4)	10 Sep 2020 17:15:32

US3912121

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1984'	Amy Collins (b) (4)	10 Sep 2020 17:15:32

US3912121

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:15:32

US3912121

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1982'	System	10 Sep 2020 17:15:32

US3912121

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1982'	System	10 Sep 2020 17:15:32

US3912121

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1984'	System	10 Sep 2020 17:15:32

US3912121

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1984'	System	10 Sep 2020 17:15:32

US3912121

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Gallbladder removal - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:17:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:17:48
Data point term sent to Coder	System	10 Sep 2020 17:17:00
User entered 'GALLBLADDER REMOVAL'	Amy Collins (b) (4)	10 Sep 2020 17:16:42

US3912121

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1995'	Amy Collins (b) (4)	10 Sep 2020 17:16:42

US3912121

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:16:42

US3912121

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 17:16:42

US3912121

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1995'	Amy Collins (b) (4)	10 Sep 2020 17:16:42

US3912121

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:16:42

US3912121

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1995'	System	10 Sep 2020 17:16:42

US3912121

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1995'	System	10 Sep 2020 17:16:42

US3912121

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1995'	System	10 Sep 2020 17:16:42

US3912121

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1995'	System	10 Sep 2020 17:16:42

US3912121

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac therapeutic procedures NEC, PT: Cardiac ablation, LLT: Cardiac ablation - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:20:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:20:43
Data point term sent to Coder	System	10 Sep 2020 17:19:06
User entered 'HEART ABLATION'	Amy Collins (b) (4)	10 Sep 2020 17:18:33

US3912121

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'UN May 2012' reason for change: Data Entry Error	Sandra Clancy (b) (4)	25 Feb 2021 00:14:36
Signature has been broken.	Sandra Clancy (b) (4)	25 Feb 2021 00:12:28
User entered 'UN Oct 2012' reason for change: Data Entry Error	Sandra Clancy (b) (4)	25 Feb 2021 00:12:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2011'	Amy Collins (b) (4)	10 Sep 2020 17:18:33

US3912121

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:18:33

US3912121

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 17:18:33

US3912121

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'UN May 2012' reason for change: Data Entry Error	Sandra Clancy (b) (4)	25 Feb 2021 00:14:36
Signature has been broken.	Sandra Clancy (b) (4)	25 Feb 2021 00:12:28
User entered 'UN Oct 2012' reason for change: Data Entry Error	Sandra Clancy (b) (4)	25 Feb 2021 00:12:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2011'	Amy Collins (b) (4)	10 Sep 2020 17:18:33

US3912121

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:18:33

US3912121

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'May 2012'	System	25 Feb 2021 00:14:36
User entered 'Oct 2012'	System	25 Feb 2021 00:12:28
User entered 'Jan 2011'	System	10 Sep 2020 17:18:33

US3912121

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2012'	System	25 Feb 2021 00:12:28
User entered '2011'	System	10 Sep 2020 17:18:33

US3912121

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'May 2012'	System	25 Feb 2021 00:14:36
User entered 'Oct 2012'	System	25 Feb 2021 00:12:28
User entered 'Jan 2011'	System	10 Sep 2020 17:18:33

US3912121

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2012'	System	25 Feb 2021 00:12:28
User entered '2011'	System	10 Sep 2020 17:18:33

US3912121

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:20:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:20:47
Data point term sent to Coder	System	10 Sep 2020 17:20:07
User entered 'HYPERTENSION'	Amy Collins (b) (4)	10 Sep 2020 17:19:46

US3912121

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2015'	Amy Collins (b) (4)	10 Sep 2020 17:19:46

US3912121

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:19:46

US3912121

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 17:19:46

US3912121

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 17:19:46

US3912121

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:19:46

US3912121

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2015'	System	10 Sep 2020 17:19:46

US3912121

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2015'	System	10 Sep 2020 17:19:46

US3912121

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:19:46

US3912121

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:19:46

US3912121

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:21:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:21:39
Data point term sent to Coder	System	10 Sep 2020 17:21:08
User entered 'ATRIAL FIBRILLATION'	Amy Collins (b) (4)	10 Sep 2020 17:20:26

US3912121

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2011'	Amy Collins (b) (4)	10 Sep 2020 17:20:26

US3912121

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:20:26

US3912121

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 17:20:26

US3912121

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 17:20:26

US3912121

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:20:26

US3912121

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2011'	System	10 Sep 2020 17:20:26

US3912121

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2011'	System	10 Sep 2020 17:20:26

US3912121

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:20:26

US3912121

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:20:26

US3912121

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 07:06:34
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:56:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:22:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:22:43
Data point term sent to Coder	System	10 Sep 2020 17:22:09
User entered 'ARTHRITIS'	Amy Collins (b) (4) (b) (4)	10 Sep 2020 17:21:19

US3912121

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2009'	Amy Collins (b) (4)	10 Sep 2020 17:21:19

US3912121

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:21:19

US3912121

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 17:21:19

US3912121

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 17:21:19

US3912121

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:21:19

US3912121

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2009'	System	10 Sep 2020 17:21:19

US3912121

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2009'	System	10 Sep 2020 17:21:19

US3912121

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:21:19

US3912121

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	10 Sep 2020 17:21:19

US3912121

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 23:21:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 23:21:26
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:26:17
Data point term sent to Coder	System	13 Oct 2020 21:29:41
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'INFORMATION UPDATED' (Site from DM).	Amy Collins (b) (4)	13 Oct 2020 21:29:06
Coding entries removed.	Amy Collins (b) (4)	13 Oct 2020 21:28:49
User entered 'LEFT KNEE REPLACEMENT (SECONDARY TO ARTHRITIS)' reason for change: New Information	Amy Collins (b) (4)	13 Oct 2020 21:28:49
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:51:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:39:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:39:40
Data point term sent to Coder	System	10 Sep 2020 17:39:03

US3912121

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
User entered 'LEFT KNEE REPLACEMENT'	Amy Collins (b) (4) (b) (4)	10 Sep 2020 17:38:25

US3912121

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2009'	Amy Collins (b) (4)	10 Sep 2020 17:38:25

US3912121

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:38:25

US3912121

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 17:38:25

US3912121

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:17:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2009'	Amy Collins (b) (4)	10 Sep 2020 17:38:25

US3912121

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:38:25

US3912121

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:17:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2009'	System	10 Sep 2020 17:38:25

US3912121

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:17:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2009'	System	10 Sep 2020 17:38:25

US3912121

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:17:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2009'	System	10 Sep 2020 17:38:25

US3912121

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2009'	System	10 Sep 2020 17:38:25

US3912121

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 23:12:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 23:12:19
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:26:32
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'INFORMATION UPDATED' (Site from DM).	Amy Collins (b) (4)	13 Oct 2020 21:29:49
Data point term sent to Coder	System	13 Oct 2020 21:29:42
Coding entries removed.	Amy Collins (b) (4)	13 Oct 2020 21:29:40
User entered 'LEFT HIP REPLACEMENT (SECONDARY TO ARTHRITIS)' reason for change: New Information	Amy Collins (b) (4)	13 Oct 2020 21:29:40
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:52:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:41:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:41:39
Data point term sent to Coder	System	10 Sep 2020 17:41:06

US3912121

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
User entered 'LEFT HIP REPLACEMENT'	(b) (4), (b) (6)	10 Sep 2020 17:40:06

US3912121

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2010'	Amy Collins (b) (4)	10 Sep 2020 17:40:06

US3912121

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:40:06

US3912121

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 17:40:06

US3912121

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2010'	Amy Collins (b) (4)	10 Sep 2020 17:40:06

US3912121

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:40:06

US3912121

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2010'	System	10 Sep 2020 17:40:06

US3912121

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2010'	System	10 Sep 2020 17:40:06

US3912121

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2010'	System	10 Sep 2020 17:40:06

US3912121

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2010'	System	10 Sep 2020 17:40:06

US3912121

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 08:55:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 08:55:48
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 09:26:45
Data point term sent to Coder	System	13 Oct 2020 21:30:43
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'INFORMATION UPDATED' (Site from DM).	Amy Collins (b) (4)	13 Oct 2020 21:30:22
Coding entries removed.	Amy Collins (b) (4)	13 Oct 2020 21:30:12
User entered 'RIGHT KNEE REPLACEMENT (SECONDARY TO ARTHRITIS)' reason for change: New Information	Amy Collins (b) (4)	13 Oct 2020 21:30:12
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:52:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:41:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:41:38
Data point term sent to Coder	System	10 Sep 2020 17:41:08

US3912121

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
User entered 'RIGHT KNEE REPLACEMENT'	(b) (4), (b) (6)	10 Sep 2020 17:40:58

US3912121

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2015'	Amy Collins (b) (4)	10 Sep 2020 17:40:58

US3912121

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:40:58

US3912121

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 17:40:58

US3912121

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2015'	Amy Collins (b) (4)	10 Sep 2020 17:40:58

US3912121

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:40:58

US3912121

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2015'	System	10 Sep 2020 17:40:58

US3912121

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2015'	System	10 Sep 2020 17:40:58

US3912121

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2015'	System	10 Sep 2020 17:40:58

US3912121

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2015'	System	10 Sep 2020 17:40:58

US3912121

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder arthroplasty, LLT: Shoulder replacement - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:42:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:42:42
Data point term sent to Coder	System	10 Sep 2020 17:42:14
User entered 'RIGHT SHOULDER REPLACEMENT'	Amy Collins (b) (4)	10 Sep 2020 17:41:55

US3912121

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2017'	Amy Collins (b) (4)	10 Sep 2020 17:41:55

US3912121

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:41:55

US3912121

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 17:41:55

US3912121

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:17:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2017'	Amy Collins (b) (4)	10 Sep 2020 17:41:55

US3912121

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:41:55

US3912121

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:17:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2017'	System	10 Sep 2020 17:41:55

US3912121

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:17:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2017'	System	10 Sep 2020 17:41:55

US3912121

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:17:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2017'	System	10 Sep 2020 17:41:55

US3912121

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2017'	System	10 Sep 2020 17:41:55

US3912121

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Injury to shoulder NOS - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 19:33:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 19:33:12
Data point term sent to Coder	System	10 Sep 2020 17:43:15
User entered 'FALL-SHOULDER INJURY (RIGHT)'	Amy Collins (b) (4)	10 Sep 2020 17:42:48

US3912121

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2017'	Amy Collins (b) (4)	10 Sep 2020 17:42:48

US3912121

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:42:48

US3912121

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 17:42:48

US3912121

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 2017'	Amy Collins (b) (4)	10 Sep 2020 17:42:48

US3912121

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:42:48

US3912121

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2017'	System	10 Sep 2020 17:42:48

US3912121

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2017'	System	10 Sep 2020 17:42:48

US3912121

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 2017'	System	10 Sep 2020 17:42:48

US3912121

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2017'	System	10 Sep 2020 17:42:48

US3912121

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:45:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:45:46
Data point term sent to Coder	System	10 Sep 2020 17:44:19
User entered 'GALL STONES'	Amy Collins (b) (4)	10 Sep 2020 17:43:24

US3912121

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1994'	Amy Collins (b) (4)	10 Sep 2020 17:43:24

US3912121

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:43:24

US3912121

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 17:43:24

US3912121

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:17:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1995'	Amy Collins (b) (4)	10 Sep 2020 17:43:24

US3912121

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:43:24

US3912121

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:17:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1994'	System	10 Sep 2020 17:43:24

US3912121

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:17:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1994'	System	10 Sep 2020 17:43:24

US3912121

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:17:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1995'	System	10 Sep 2020 17:43:24

US3912121

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1995'	System	10 Sep 2020 17:43:24

US3912121

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Sep 2020 04:56:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 04:56:47
Data point term sent to Coder	System	10 Sep 2020 17:45:26
User entered 'CATARACT SURGERY-RIGHT'	Amy Collins (b) (4) (b) (4)	10 Sep 2020 17:45:24

US3912121

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN May 2020'	Amy Collins (b) (4)	10 Sep 2020 17:45:24

US3912121

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:45:24

US3912121

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 17:45:24

US3912121

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:17:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN May 2020'	Amy Collins (b) (4)	10 Sep 2020 17:45:24

US3912121

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:45:24

US3912121

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:17:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'May 2020'	System	10 Sep 2020 17:45:24

US3912121

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:17:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2020'	System	10 Sep 2020 17:45:24

US3912121

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:17:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'May 2020'	System	10 Sep 2020 17:45:24

US3912121

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2020'	System	10 Sep 2020 17:45:24

US3912121

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 04:56:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 04:56:46
Data point term sent to Coder	System	10 Sep 2020 17:47:29
User entered 'CATARACT SURGERY-LEFT'	Amy Collins (b) (4)	10 Sep 2020 17:46:39

US3912121

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN Feb 2020'	Amy Collins (b) (4)	10 Sep 2020 17:46:39

US3912121

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:46:39

US3912121

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 17:46:39

US3912121

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:17:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN Feb 2020'	Amy Collins (b) (4)	10 Sep 2020 17:46:39

US3912121

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:46:39

US3912121

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:17:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Feb 2020'	System	10 Sep 2020 17:46:39

US3912121

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:17:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2020'	System	10 Sep 2020 17:46:39

US3912121

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:17:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Feb 2020'	System	10 Sep 2020 17:46:39

US3912121

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2020'	System	10 Sep 2020 17:46:39

US3912121

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	11 Sep 2020 04:56:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 04:56:47
Data point term sent to Coder	System	10 Sep 2020 17:53:45
User entered 'CATARACTS-BILATERAL'	Amy Collins (b) (4) (b) (4)	10 Sep 2020 17:53:16

US3912121

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN Feb 2020'	Amy Collins (b) (4)	10 Sep 2020 17:53:16

US3912121

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:53:16

US3912121

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 17:53:16

US3912121

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:17:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN May 2020'	Amy Collins (b) (4)	10 Sep 2020 17:53:16

US3912121

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 17:53:16

US3912121

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:17:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Feb 2020'	System	10 Sep 2020 17:53:16

US3912121

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:17:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2020'	System	10 Sep 2020 17:53:16

US3912121

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:17:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'May 2020'	System	10 Sep 2020 17:53:16

US3912121

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2020'	System	10 Sep 2020 17:53:16

US3912121

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:17:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac therapeutic procedures NEC, PT: Cardioversion, LLT: Electrical cardioversion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 10:33:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 10:33:43
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	09 Mar 2021 19:56:43
Data point term sent to Coder	System	25 Feb 2021 00:18:43
User entered 'DIRECT CURRENT CARDIOVERSION (1st in Feb 2012; 2nd May 2012)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:18:02
Data point term sent to Coder	System	25 Feb 2021 00:17:41
User entered 'direct current cardioversion'	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:17:13

US3912121

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	Sandra Clancy (b) (4)	25 Feb 2021 00:17:13

US3912121

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'I'	Sandra Clancy (b) (4)	25 Feb 2021 00:17:13

US3912121

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'No (N)'	Sandra Clancy (b) (4)	25 Feb 2021 00:17:13

US3912121

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:17:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	Sandra Clancy (b) (4)	25 Feb 2021 00:17:13

US3912121

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'I'	Sandra Clancy (b) (4)	25 Feb 2021 00:17:13

US3912121

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:17:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	25 Feb 2021 00:17:13

US3912121

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:17:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	25 Feb 2021 00:17:13

US3912121

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:17:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	25 Feb 2021 00:17:13

US3912121

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	25 Feb 2021 00:17:13

US3912121

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Joint range of motion decreased, LLT: Joint range of motion decreased - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 13:25:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	29 Mar 2021 13:25:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
Data point term sent to Coder	(b) (4)	26 Mar 2021 20:26:00
User entered 'decreased range of motion right hip'	System	26 Mar 2021 20:25:55
	(b) (4), (b) (6)	

US3912121

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:25:55

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Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:25:55

US3912121

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:25:55

US3912121

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:17:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:25:55

US3912121

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:25:55

US3912121

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:17:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Sep 2020'	System	26 Mar 2021 20:25:55

US3912121

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:17:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2020'	System	26 Mar 2021 20:25:55

US3912121

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:17:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	26 Mar 2021 20:25:55

US3912121

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	26 Mar 2021 20:25:55

US3912121

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Endocrine procedural complications, PT: Post procedural hypothyroidism, LLT: Post surgical hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 13:41:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 13:41:08
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	28 Mar 2021 16:23:10
Data point term sent to Coder	System	26 Mar 2021 20:40:26
User entered 'Hypothyroidism (Post-surgical)'	(b) (4), (b) (6)	26 Mar 2021 20:39:42

US3912121

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered 'un UNK 1984'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:39:42

US3912121

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:39:42

US3912121

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:39:42

US3912121

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:17:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:39:42

US3912121

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:39:42

US3912121

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:17:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jan 1984'	System	26 Mar 2021 20:39:42

US3912121

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:17:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '1984'	System	26 Mar 2021 20:39:42

US3912121

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:17:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	26 Mar 2021 20:39:42

US3912121

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	26 Mar 2021 20:39:42

US3912121

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:17:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
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) (b) (4)	29 Mar 2021 13:26:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 13:26:05
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	28 Mar 2021 16:23:10
Data point term sent to Coder	System	26 Mar 2021 20:58:04
User entered 'degenerative joint disease, right hip'	(b) (4), (b) (6)	26 Mar 2021 20:57:09

US3912121

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered 'un Jun 2020'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:57:09

US3912121

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:57:09

US3912121

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:17:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:57:09

US3912121

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:17:58

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:57:09

US3912121

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:17:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:57:09

US3912121

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:17:58

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'Jun 2020'	System	26 Mar 2021 20:57:09

US3912121

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:17:58

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '2020'	System	26 Mar 2021 20:57:09

US3912121

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:17:58

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	26 Mar 2021 20:57:09

US3912121

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 10:17:58

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered empty.	System	26 Mar 2021 20:57:09

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 17:58:13

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '08 Sep 2020'	Amy Collins (b) (4)	10 Sep 2020 17:58:13

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '10:30'	Amy Collins (b) (4)	10 Sep 2020 17:58:13

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '08 Sep 2020 10:30'	System	10 Sep 2020 17:58:13

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '64.0' in	Amy Collins (b) (4)	10 Sep 2020 17:58:13
DataPoint set to visible.	System	08 Sep 2020 19:03:31

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '155.0' lb	Amy Collins (b) (4)	10 Sep 2020 17:58:13
DataPoint set to visible.	System	08 Sep 2020 19:03:31

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered '26.66132'	System	10 Sep 2020 17:58:13
DataPoint set to visible.	System	08 Sep 2020 19:03:31

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'kg/m2'	System	10 Sep 2020 17:58:13
DataPoint set to visible.	System	08 Sep 2020 19:03:31

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Kindly consider manually type as "ND". The fields are free text and enterable. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 11:41:35
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Kindly consider manually type as "ND". The fields are free text and enterable. Thank you.' answered with 'data updated' (Site from DM).	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:01:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:01:07
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Kindly consider manually type as "ND". The fields are free text and enterable. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 04:09:00
User entered '36.1' C	Amy Collins (b) (4) (b) (4)	10 Sep 2020 17:58:13

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty; reason for change Data Entry Error	Tina Rountree (b) (4)	03 Oct 2020 15:01:07
User entered 'Oral (Oral)'	Amy Collins (b) (4)	10 Sep 2020 17:58:13

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 17:58:13

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Oct 2020 15:01:07
User entered '54'	Tina Rountree (b) (4)	10 Sep 2020 17:58:13
	(b) (4)	

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'bpm'	System	10 Sep 2020 17:58:13

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Oct 2020 15:01:07
User entered '16'	Tina Rountree (b) (4)	10 Sep 2020 17:58:13
	(b) (4)	

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'breaths/min'	System	10 Sep 2020 17:58:13

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Oct 2020 15:01:07
User entered '136'	Tina Rountree (b) (4)	10 Sep 2020 17:58:13
	(b) (4)	

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'mmHg'	System	10 Sep 2020 17:58:13

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Oct 2020 15:01:07
User entered '66'	Tina Rountree (b) (4)	10 Sep 2020 17:58:13
	(b) (4)	

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User entered 'mmHg'	System	10 Sep 2020 17:58:13

US3912121

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55

US3912121

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 17:59:26

US3912121

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '08 Sep 2020'	Amy Collins (b) (4)	10 Sep 2020 17:59:26

US3912121

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '08 Sep 2020'	Amy Collins (b) (4)	10 Sep 2020 18:02:35

US3912121

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:17:58

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:02:35

US3912121

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:17:58

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Surgically sterile (SURGICALLY STERILE)'	Amy Collins (b) (4)	10 Sep 2020 18:02:35

US3912121

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:17:58

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 18:02:35

US3912121

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:17:58

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'UN UNK 1984'	Amy Collins (b) (4)	10 Sep 2020 18:02:35

US3912121

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:17:58

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 18:02:35

US3912121

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:17:58

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 18:02:35

US3912121

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 10:17:58

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 18:02:35

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

[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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '> 65 YRS OF AGE'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'I'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

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 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '0'	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:17:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:52:55
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 18:04:04

US3912121

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:45

US3912121

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:03:45

US3912121

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

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 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User entered 'Clinic (Clinic)' reason for change:	System	08 Sep 2020 19:03:49
Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:03:49
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).		
User entered empty.	System	08 Sep 2020 19:03:45
	(b) (4), (b) (6)	08 Sep 2020 19:03:45

US3912121

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'VISIT1'	System	08 Sep 2020 19:03:45

US3912121

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:58

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 17:04:57

US3912121

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:58

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '190047'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 17:04:57

US3912121

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:58

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 17:04:57

US3912121

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:58

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 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:06:07

US3912121

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:58

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 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:06:07

US3912121

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:58

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:06:07

US3912121

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:58

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:06:07

US3912121

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:58

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:06:07

US3912121

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:17:58

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Mia Rountree (b) (4)	12 Oct 2020 19:52:57
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:37:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:37:57

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 11:34:55
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly. Thank you.' answered with 'data updated' (Site from DM).	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:01:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:01:37
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 04:09:22
User entered '64.0' in	Amy Collins (b) (4) (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Oct 2020 15:01:37
User entered '155.0' lb	Tina Rountree (b) (4)	10 Sep 2020 18:09:37
	(b) (4)	

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 11:34:55
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly. Thank you.' answered with 'data updated' (Site from DM).	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:01:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:01:37
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 04:09:22
User entered '64.0' in	Amy Collins (b) (4) (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Oct 2020 15:01:37
User entered '155.0' lb	Tina Rountree (b) (4)	10 Sep 2020 18:09:37
	(b) (4)	

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User accepted default value 'Pre-Dose (PREDOSE)'	Amy Collins (b) (4) (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '08 Sep 2020'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '10:30'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered '08 Sep 2020 10:30'	System	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '36.1' C	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Oral (Oral)'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '54'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'bpm'	System	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '16'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'breaths/min'	System	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '136'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'mmHg'	System	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '66'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'mmHg'	System	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 11:34:55
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly. Thank you.' answered with 'data updated' (Site from DM).	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:01:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:01:37
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 04:09:22
User entered '64.0' in	Amy Collins (b) (4) (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Oct 2020 15:01:37
User entered '155.0' lb	Tina Rountree (b) (4)	10 Sep 2020 18:09:37
	(b) (4)	

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User accepted default value 'Post-Dose (POSTDOSE)'	Amy Collins (b) (4) (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '08 Sep 2020'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '14:11'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered '08 Sep 2020 14:11'	System	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '97.6' F	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Oral (Oral)'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '56'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'bpm'	System	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '16'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'breaths/min'	System	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '119'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'mmHg'	System	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '79'	Amy Collins (b) (4)	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'mmHg'	System	10 Sep 2020 18:09:37

US3912121

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	10 Sep 2020 18:09:48

US3912121

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 18:09:48

US3912121

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:04:24

US3912121

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:04:24

US3912121

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

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 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:04:24

US3912121

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 19:04:24

US3912121

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '08 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:04:24

US3912121

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '12:54'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:04:24

US3912121

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered '08 Sep 2020 12:54'	System	08 Sep 2020 19:04:24

US3912121

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 19:04:24

US3912121

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'ONCE'	System	08 Sep 2020 19:04:24

US3912121

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 19:04:24

US3912121

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 18:10:56

US3912121

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '08 Sep 2020'	Amy Collins (b) (4)	10 Sep 2020 18:10:56

US3912121

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '12:12'	Amy Collins (b) (4)	10 Sep 2020 18:10:56

US3912121

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered '08 Sep 2020 12:12'	System	10 Sep 2020 18:10:56

US3912121

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:17:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '08 Sep 2020'	Amy Collins (b) (4)	10 Sep 2020 18:11:16

US3912121

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amy Collins (b) (4) (b) (4)	10 Sep 2020 18:11:16

US3912121

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 18:11:16

US3912121

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '12:17'	Amy Collins (b) (4)	10 Sep 2020 18:11:16

US3912121

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered '08 Sep 2020 12:17'	System	10 Sep 2020 18:11:16

US3912121

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amy Collins (b) (4) (b) (4)	10 Sep 2020 18:11:16

US3912121

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
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	10 Sep 2020 18:11:26
User entered 'No (N)' reason for change: Data Entry Error	Amy Collins (b) (4)	10 Sep 2020 18:11:26
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	10 Sep 2020 18:11:16
	Amy Collins (b) (4)	10 Sep 2020 18:11:16
	(b) (4)	

US3912121

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	10 Sep 2020 18:11:16

US3912121

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered empty.	System	10 Sep 2020 18:11:16

US3912121

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	10 Sep 2020 18:19:05

US3912121

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered '1'	System	10 Sep 2020 18:19:05

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:14:19', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '1a854b95-047c-42dc-a645-a03a2e713fb0' User entered 'Yes (Y)'	System	08 Sep 2020 19:15:08
	System	08 Sep 2020 19:15:08

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:14:42', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '1a854b95-047c-42dc-a645-a03a2e713fb0' User entered '97.6'	System	08 Sep 2020 19:15:08
	System	08 Sep 2020 19:15:08

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:14:51', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '1a854b95-047c-42dc-a645-a03a2e713fb0' User entered 'No (N)'	System	08 Sep 2020 19:15:08
	System	08 Sep 2020 19:15:08

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:15:04', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '1a854b95-047c-42dc-a645-a03a2e713fb0' User entered '08 Sep 2020 14:15'	System	08 Sep 2020 19:15:08
	System	08 Sep 2020 19:15:08

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Sep 2020 13:14'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Sep 2020 15:44'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:54:10', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'fe3b50fa-a20d-4004-b1e2-396e75f96c51' User entered 'Yes (Y)'	System	09 Sep 2020 01:54:57
	System	09 Sep 2020 01:54:57

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:54:24', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'fe3b50fa-a20d-4004-b1e2-396e75f96c51' User entered '97.4'	System	09 Sep 2020 01:54:57
	System	09 Sep 2020 01:54:57

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:54:36', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'fe3b50fa-a20d-4004-b1e2-396e75f96c51'	System	09 Sep 2020 01:54:57
User entered 'No (N)'	System	09 Sep 2020 01:54:57

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:54:55', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'fe3b50fa-a20d-4004-b1e2-396e75f96c51'	System	09 Sep 2020 01:54:57
User entered '08 Sep 2020 20:54'	System	09 Sep 2020 01:54:57

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Sep 2020 16:39'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 2'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:02:49', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '4fc0e66e-f43b-4821-910d-9d074bb3dba1' User entered 'Yes (Y)'	System	10 Sep 2020 02:04:09
	System	10 Sep 2020 02:04:09

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:03:09', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '4fc0e66e-f43b-4821-910d-9d074bb3dba1' User entered '96.3'	System	10 Sep 2020 02:04:09
	System	10 Sep 2020 02:04:09

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:03:18', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '4fc0e66e-f43b-4821-910d-9d074bb3dba1' User entered 'No (N)'	System	10 Sep 2020 02:04:09
	System	10 Sep 2020 02:04:09

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:04:01', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '4fc0e66e-f43b-4821-910d-9d074bb3dba1' User entered '09 Sep 2020 21:04'	System	10 Sep 2020 02:04:09
	System	10 Sep 2020 02:04:09

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 3'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:17:43', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '8ad38be2-e0a4-4e4c-8b77-7c17c87492bb' User entered 'Yes (Y)'	System	11 Sep 2020 01:18:09
	System	11 Sep 2020 01:18:09

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:17:55', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '8ad38be2-e0a4-4e4c-8b77-7c17c87492bb' User entered '97.3'	System	11 Sep 2020 01:18:09
	System	11 Sep 2020 01:18:09

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:18:02', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '8ad38be2-e0a4-4e4c-8b77-7c17c87492bb'	System	11 Sep 2020 01:18:09
User entered 'No (N)'	System	11 Sep 2020 01:18:09

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:18:07', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '8ad38be2-e0a4-4e4c-8b77-7c17c87492bb' User entered '10 Sep 2020 19:18'	System	11 Sep 2020 01:18:09
	System	11 Sep 2020 01:18:09

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 4'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:04:16', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '111cc274-2cba-49ce-b017-9be68d6a51e5' User entered 'Yes (Y)'	System	12 Sep 2020 01:04:55
	System	12 Sep 2020 01:04:55

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:04:28', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '111cc274-2cba-49ce-b017-9be68d6a51e5' User entered '96.9'	System	12 Sep 2020 01:04:55
	System	12 Sep 2020 01:04:55

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:04:38', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '111cc274-2cba-49ce-b017-9be68d6a51e5'	System	12 Sep 2020 01:04:55
User entered 'No (N)'	System	12 Sep 2020 01:04:55

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:04:42', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '111cc274-2cba-49ce-b017-9be68d6a51e5'	System	12 Sep 2020 01:04:55
User entered '11 Sep 2020 19:04'	System	12 Sep 2020 01:04:55

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 5'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:33:36', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0db409a0-e6a3-42ec-8405-1a22a3775807' User entered 'Yes (Y)'	System	13 Sep 2020 00:38:05
	System	13 Sep 2020 00:38:05

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:33:51', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0db409a0-e6a3-42ec-8405-1a22a3775807' User entered '96.7'	System	13 Sep 2020 00:38:05
	System	13 Sep 2020 00:38:05

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:33:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0db409a0-e6a3-42ec-8405-1a22a3775807' User entered 'No (N)'	System	13 Sep 2020 00:38:05
	System	13 Sep 2020 00:38:05

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:34:04', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0db409a0-e6a3-42ec-8405-1a22a3775807' User entered '12 Sep 2020 18:34'	System	13 Sep 2020 00:38:05
	System	13 Sep 2020 00:38:05

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 6'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:57:29', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '419ff3cc-b26c-47c9-8dc1-f1cad57be4de' User entered 'Yes (Y)'	System	14 Sep 2020 01:58:01
	System	14 Sep 2020 01:58:01

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:57:47', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '419ff3cc-b26c-47c9-8dc1-f1cad57be4de' User entered '97.6'	System	14 Sep 2020 01:58:01
	System	14 Sep 2020 01:58:01

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:57:52', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '419ff3cc-b26c-47c9-8dc1-f1cad57be4de'	System	14 Sep 2020 01:58:01
User entered 'No (N)'	System	14 Sep 2020 01:58:01

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:57:55', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '419ff3cc-b26c-47c9-8dc1-f1cad57be4de' User entered '13 Sep 2020 19:57'	System	14 Sep 2020 01:58:01
	System	14 Sep 2020 01:58:01

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 7'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:50:36', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '61ece052-8acc-4ecb-9ea3-63a2eac8969b' User entered 'Yes (Y)'	System	15 Sep 2020 05:51:05
	System	15 Sep 2020 05:51:05

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:50:49', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '61ece052-8acc-4ecb-9ea3-63a2eac8969b' User entered '98.1'	System	15 Sep 2020 05:51:05
	System	15 Sep 2020 05:51:05

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:50:59', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '61ece052-8acc-4ecb-9ea3-63a2eac8969b'	System	15 Sep 2020 05:51:05
User entered 'No (N)'	System	15 Sep 2020 05:51:05

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:03', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '61ece052-8acc-4ecb-9ea3-63a2eac8969b' User entered '15 Sep 2020 00:51'	System	15 Sep 2020 05:51:05
	System	15 Sep 2020 05:51:05

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:15:36', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6a088e33-16f6-4a15-a28e-39b5f5177c82'	System	08 Sep 2020 19:16:27
User entered 'None (1)'	System	08 Sep 2020 19:16:27

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:15:43', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6a088e33-16f6-4a15-a28e-39b5f5177c82'	System	08 Sep 2020 19:16:27
User entered 'No (N)'	System	08 Sep 2020 19:16:27

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:15:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6a088e33-16f6-4a15-a28e-39b5f5177c82'	System	08 Sep 2020 19:16:27
User entered 'No (N)'	System	08 Sep 2020 19:16:27

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:16:07', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6a088e33-16f6-4a15-a28e-39b5f5177c82'	System	08 Sep 2020 19:16:27
User entered 'None (1)'	System	08 Sep 2020 19:16:27

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:16:23', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6a088e33-16f6-4a15-a28e-39b5f5177c82'	System	08 Sep 2020 19:16:27
User entered '08 Sep 2020 14:16'	System	08 Sep 2020 19:16:27

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Sep 2020 13:14'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Sep 2020 15:44'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:55:09', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '974da7e7-86d7-4286-9f1f-9f57b5d8751c' User entered 'None (1)'	System	09 Sep 2020 01:55:49
	System	09 Sep 2020 01:55:49

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:55:14', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '974da7e7-86d7-4286-9f1f-9f57b5d8751c'	System	09 Sep 2020 01:55:49
User entered 'No (N)'	System	09 Sep 2020 01:55:49

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:55:23', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '974da7e7-86d7-4286-9f1f-9f57b5d8751c'	System	09 Sep 2020 01:55:49
User entered 'No (N)'	System	09 Sep 2020 01:55:49

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:55:33', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '974da7e7-86d7-4286-9f1f-9f57b5d8751c'	System	09 Sep 2020 01:55:49
User entered 'None (1)'	System	09 Sep 2020 01:55:49

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:55:47', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '974da7e7-86d7-4286-9f1f-9f57b5d8751c'	System	09 Sep 2020 01:55:49
User entered '08 Sep 2020 20:55'	System	09 Sep 2020 01:55:49

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Sep 2020 16:39'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 2'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:04:11', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e309167c-12db-436f-ab04-b05e85ac6538'	System	10 Sep 2020 02:04:44
User entered 'None (1)'	System	10 Sep 2020 02:04:44

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:04:15', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e309167c-12db-436f-ab04-b05e85ac6538' User entered 'No (N)'	System	10 Sep 2020 02:04:44
	System	10 Sep 2020 02:04:44

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:04:26', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e309167c-12db-436f-ab04-b05e85ac6538' User entered 'No (N)'	System	10 Sep 2020 02:04:44
	System	10 Sep 2020 02:04:44

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:04:36', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e309167c-12db-436f-ab04-b05e85ac6538' User entered 'None (1)'	System	10 Sep 2020 02:04:44
	System	10 Sep 2020 02:04:44

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:04:40', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e309167c-12db-436f-ab04-b05e85ac6538' User entered '09 Sep 2020 21:04'	System	10 Sep 2020 02:04:44
	System	10 Sep 2020 02:04:44

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 3'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:18:15', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0cae3bab-11a9-4e34-8a6e-de6372b3cb65' User entered 'None (1)'	System	11 Sep 2020 01:18:42
	System	11 Sep 2020 01:18:42

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:18:22', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0cae3bab-11a9-4e34-8a6e-de6372b3cb65'	System	11 Sep 2020 01:18:42
User entered 'No (N)'	System	11 Sep 2020 01:18:42

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:18:30', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0cae3bab-11a9-4e34-8a6e-de6372b3cb65'	System	11 Sep 2020 01:18:42
User entered 'No (N)'	System	11 Sep 2020 01:18:42

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:18:36', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0cae3bab-11a9-4e34-8a6e-de6372b3cb65' User entered 'None (1)'	System	11 Sep 2020 01:18:42
	System	11 Sep 2020 01:18:42

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:18:39', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0cae3bab-11a9-4e34-8a6e-de6372b3cb65'	System	11 Sep 2020 01:18:42
User entered '10 Sep 2020 19:18'	System	11 Sep 2020 01:18:42

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 4'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:05:37', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e0fbd9b3-9ff8-451d-87d2-d2b74a0dfca5' User entered 'None (1)'	System	13 Sep 2020 00:38:04
	System	13 Sep 2020 00:38:04

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:05:40', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e0fbd9b3-9ff8-451d-87d2-d2b74a0dfca5'	System	13 Sep 2020 00:38:04
User entered 'No (N)'	System	13 Sep 2020 00:38:04

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:06:12', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e0fbd9b3-9ff8-451d-87d2-d2b74a0dfca5'	System	13 Sep 2020 00:38:04
User entered 'No (N)'	System	13 Sep 2020 00:38:04

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:06:20', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e0fbd9b3-9ff8-451d-87d2-d2b74a0dfca5' User entered 'None (1)'	System	13 Sep 2020 00:38:04
	System	13 Sep 2020 00:38:04

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:06:24', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e0fbd9b3-9ff8-451d-87d2-d2b74a0dfca5' User entered '11 Sep 2020 19:06'	System	13 Sep 2020 00:38:04
	System	13 Sep 2020 00:38:04

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 5'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:34:10', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97c99412-fdc7-44d4-8347-beb3dd3c621a' User entered 'None (1)'	System	13 Sep 2020 00:38:09
	System	13 Sep 2020 00:38:09

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:34:14', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97c99412-fdc7-44d4-8347-beb3dd3c621a' User entered 'No (N)'	System	13 Sep 2020 00:38:09
	System	13 Sep 2020 00:38:09

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:34:18', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97c99412-fdc7-44d4-8347-beb3dd3c621a' User entered 'No (N)'	System	13 Sep 2020 00:38:09
	System	13 Sep 2020 00:38:09

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:34:23', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97c99412-fdc7-44d4-8347-beb3dd3c621a' User entered 'None (1)'	System	13 Sep 2020 00:38:09
	System	13 Sep 2020 00:38:09

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:34:26', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97c99412-fdc7-44d4-8347-beb3dd3c621a' User entered '12 Sep 2020 18:34'	System	13 Sep 2020 00:38:09
	System	13 Sep 2020 00:38:09

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 6'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:58:04', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '219c9509-bbf2-43cd-a3a9-74bf2856ebdc' User entered 'None (1)'	System	14 Sep 2020 01:58:25
	System	14 Sep 2020 01:58:25

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:58:08', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '219c9509-bbf2-43cd-a3a9-74bf2856ebdc' User entered 'No (N)'	System	14 Sep 2020 01:58:25
	System	14 Sep 2020 01:58:25

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:58:12', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '219c9509-bbf2-43cd-a3a9-74bf2856ebdc' User entered 'No (N)'	System	14 Sep 2020 01:58:25
	System	14 Sep 2020 01:58:25

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:58:17', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '219c9509-bbf2-43cd-a3a9-74bf2856ebdc' User entered 'None (1)'	System	14 Sep 2020 01:58:25
	System	14 Sep 2020 01:58:25

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:58:23', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '219c9509-bbf2-43cd-a3a9-74bf2856ebdc' User entered '13 Sep 2020 19:58'	System	14 Sep 2020 01:58:25
	System	14 Sep 2020 01:58:25

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 7'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:07', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97a91f3d-8ece-47d8-9433-86e45b823c15' User entered 'None (1)'	System	15 Sep 2020 05:51:24
	System	15 Sep 2020 05:51:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:11', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97a91f3d-8ece-47d8-9433-86e45b823c15' User entered 'No (N)'	System	15 Sep 2020 05:51:24
	System	15 Sep 2020 05:51:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:14', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97a91f3d-8ece-47d8-9433-86e45b823c15'	System	15 Sep 2020 05:51:24
User entered 'No (N)'	System	15 Sep 2020 05:51:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:18', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97a91f3d-8ece-47d8-9433-86e45b823c15' User entered 'None (1)'	System	15 Sep 2020 05:51:24
	System	15 Sep 2020 05:51:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:22', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97a91f3d-8ece-47d8-9433-86e45b823c15' User entered '15 Sep 2020 00:51'	System	15 Sep 2020 05:51:24
	System	15 Sep 2020 05:51:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:16:35', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '354cc6e3-15ce-4ced-9885-9a39678b1a4a' User entered 'None (0)'	System	08 Sep 2020 19:17:16
	System	08 Sep 2020 19:17:16

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:16:45', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '354cc6e3-15ce-4ced-9885-9a39678b1a4a' User entered 'None (0)'	System	08 Sep 2020 19:17:16
	System	08 Sep 2020 19:17:16

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:16:49', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '354cc6e3-15ce-4ced-9885-9a39678b1a4a' User entered 'None (0)'	System	08 Sep 2020 19:17:16
	System	08 Sep 2020 19:17:16

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:16:54', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '354cc6e3-15ce-4ced-9885-9a39678b1a4a' User entered 'None (0)'	System	08 Sep 2020 19:17:16
	System	08 Sep 2020 19:17:16

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:16:58', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '354cc6e3-15ce-4ced-9885-9a39678b1a4a' User entered 'None (0)'	System	08 Sep 2020 19:17:16
	System	08 Sep 2020 19:17:16

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:17:02', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '354cc6e3-15ce-4ced-9885-9a39678b1a4a' User entered 'None (0)'	System	08 Sep 2020 19:17:16
	System	08 Sep 2020 19:17:16

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:17:08', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '354cc6e3-15ce-4ced-9885-9a39678b1a4a' User entered 'No (N)'	System	08 Sep 2020 19:17:16
	System	08 Sep 2020 19:17:16

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T14:17:12', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '354cc6e3-15ce-4ced-9885-9a39678b1a4a' User entered '08 Sep 2020 14:17'	System	08 Sep 2020 19:17:16
	System	08 Sep 2020 19:17:16

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Sep 2020 13:14'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Sep 2020 15:44'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:55:58', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '51f836fb-bf26-4393-b777-e76916e1fef0'	System	09 Sep 2020 01:56:32
User entered 'None (0)'	System	09 Sep 2020 01:56:32

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:56:01', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '51f836fb-bf26-4393-b777-e76916e1fef0'	System	09 Sep 2020 01:56:32
User entered 'None (0)'	System	09 Sep 2020 01:56:32

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:56:06', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '51f836fb-bf26-4393-b777-e76916e1fef0'	System	09 Sep 2020 01:56:32
User entered 'None (0)'	System	09 Sep 2020 01:56:32

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:56:10', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '51f836fb-bf26-4393-b777-e76916e1fef0' User entered 'None (0)'	System	09 Sep 2020 01:56:32
	System	09 Sep 2020 01:56:32

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:56:15', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '51f836fb-bf26-4393-b777-e76916e1fef0'	System	09 Sep 2020 01:56:32
User entered 'None (0)'	System	09 Sep 2020 01:56:32

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:56:18', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '51f836fb-bf26-4393-b777-e76916e1fef0'	System	09 Sep 2020 01:56:32
User entered 'None (0)'	System	09 Sep 2020 01:56:32

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:56:25', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '51f836fb-bf26-4393-b777-e76916e1fef0'	System	09 Sep 2020 01:56:32
User entered 'No (N)'	System	09 Sep 2020 01:56:32

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-08T20:56:29', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '51f836fb-bf26-4393-b777-e76916e1fef0'	System	09 Sep 2020 01:56:32
User entered '08 Sep 2020 20:56'	System	09 Sep 2020 01:56:32

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Sep 2020 16:39'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 2'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:04:48', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a4cd7bf9-88f4-4380-95f9-d25c7307f82e' User entered 'None (0)'	System	10 Sep 2020 02:05:39
	System	10 Sep 2020 02:05:39

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:04:55', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a4cd7bf9-88f4-4380-95f9-d25c7307f82e' User entered 'None (0)'	System	10 Sep 2020 02:05:39
	System	10 Sep 2020 02:05:39

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:05:05', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a4cd7bf9-88f4-4380-95f9-d25c7307f82e' User entered 'None (0)'	System	10 Sep 2020 02:05:39
	System	10 Sep 2020 02:05:39

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:05:17', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a4cd7bf9-88f4-4380-95f9-d25c7307f82e' User entered 'None (0)'	System	10 Sep 2020 02:05:39
	System	10 Sep 2020 02:05:39

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:05:22', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a4cd7bf9-88f4-4380-95f9-d25c7307f82e' User entered 'None (0)'	System	10 Sep 2020 02:05:39
	System	10 Sep 2020 02:05:39

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:05:25', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a4cd7bf9-88f4-4380-95f9-d25c7307f82e' User entered 'None (0)'	System	10 Sep 2020 02:05:39
	System	10 Sep 2020 02:05:39

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:05:29', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a4cd7bf9-88f4-4380-95f9-d25c7307f82e' User entered 'No (N)'	System	10 Sep 2020 02:05:39
	System	10 Sep 2020 02:05:39

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-09T21:05:34', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a4cd7bf9-88f4-4380-95f9-d25c7307f82e'	System	10 Sep 2020 02:05:39
User entered '09 Sep 2020 21:05'	System	10 Sep 2020 02:05:39

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 3'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:18:45', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f7a0cf1e-4ee9-427f-9724-13629f01a6f0' User entered 'None (0)'	System	11 Sep 2020 01:19:26
	System	11 Sep 2020 01:19:26

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:18:48', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f7a0cf1e-4ee9-427f-9724-13629f01a6f0'	System	11 Sep 2020 01:19:26
User entered 'None (0)'	System	11 Sep 2020 01:19:26

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:18:52', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f7a0cf1e-4ee9-427f-9724-13629f01a6f0' User entered 'None (0)'	System	11 Sep 2020 01:19:26
	System	11 Sep 2020 01:19:26

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:19:02', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f7a0cf1e-4ee9-427f-9724-13629f01a6f0' User entered 'None (0)'	System	11 Sep 2020 01:19:26
	System	11 Sep 2020 01:19:26

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:19:07', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f7a0cf1e-4ee9-427f-9724-13629f01a6f0' User entered 'None (0)'	System	11 Sep 2020 01:19:26
	System	11 Sep 2020 01:19:26

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:19:12', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f7a0cf1e-4ee9-427f-9724-13629f01a6f0'	System	11 Sep 2020 01:19:26
User entered 'None (0)'	System	11 Sep 2020 01:19:26

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:19:18', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f7a0cf1e-4ee9-427f-9724-13629f01a6f0'	System	11 Sep 2020 01:19:26
User entered 'No (N)'	System	11 Sep 2020 01:19:26

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-10T19:19:22', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f7a0cf1e-4ee9-427f-9724-13629f01a6f0'	System	11 Sep 2020 01:19:26
User entered '10 Sep 2020 19:19'	System	11 Sep 2020 01:19:26

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 4'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:06:30', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '544fe5a4-791e-4037-b1e0-095e3d51ff32'	System	13 Sep 2020 00:38:04
User entered 'None (0)'	System	13 Sep 2020 00:38:04

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:06:34', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '544fe5a4-791e-4037-b1e0-095e3d51ff32'	System	13 Sep 2020 00:38:04
User entered 'None (0)'	System	13 Sep 2020 00:38:04

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:06:39', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '544fe5a4-791e-4037-b1e0-095e3d51ff32'	System	13 Sep 2020 00:38:04
User entered 'None (0)'	System	13 Sep 2020 00:38:04

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:06:45', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '544fe5a4-791e-4037-b1e0-095e3d51ff32'	System	13 Sep 2020 00:38:04
User entered 'None (0)'	System	13 Sep 2020 00:38:04

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:06:48', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '544fe5a4-791e-4037-b1e0-095e3d51ff32'	System	13 Sep 2020 00:38:04
User entered 'None (0)'	System	13 Sep 2020 00:38:04

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:06:51', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '544fe5a4-791e-4037-b1e0-095e3d51ff32'	System	13 Sep 2020 00:38:04
User entered 'None (0)'	System	13 Sep 2020 00:38:04

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:07:00', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '544fe5a4-791e-4037-b1e0-095e3d51ff32'	System	13 Sep 2020 00:38:04
User entered 'No (N)'	System	13 Sep 2020 00:38:04

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-11T19:07:03', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '544fe5a4-791e-4037-b1e0-095e3d51ff32'	System	13 Sep 2020 00:38:04
User entered '11 Sep 2020 19:07'	System	13 Sep 2020 00:38:04

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 5'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:34:32', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '1b3aea9e-866c-4028-90a8-98a5fe54a2ef' User entered 'None (0)'	System	13 Sep 2020 00:38:12
	System	13 Sep 2020 00:38:12

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:34:38', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '1b3aea9e-866c-4028-90a8-98a5fe54a2ef' User entered 'None (0)'	System	13 Sep 2020 00:38:12
	System	13 Sep 2020 00:38:12

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:34:44', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '1b3aea9e-866c-4028-90a8-98a5fe54a2ef' User entered 'None (0)'	System	13 Sep 2020 00:38:12
	System	13 Sep 2020 00:38:12

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:34:48', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '1b3aea9e-866c-4028-90a8-98a5fe54a2ef' User entered 'None (0)'	System	13 Sep 2020 00:38:12
	System	13 Sep 2020 00:38:12

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:34:53', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '1b3aea9e-866c-4028-90a8-98a5fe54a2ef' User entered 'None (0)'	System	13 Sep 2020 00:38:12
	System	13 Sep 2020 00:38:12

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:34:56', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '1b3aea9e-866c-4028-90a8-98a5fe54a2ef' User entered 'None (0)'	System	13 Sep 2020 00:38:12
	System	13 Sep 2020 00:38:12

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:35:04', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '1b3aea9e-866c-4028-90a8-98a5fe54a2ef' User entered 'No (N)'	System	13 Sep 2020 00:38:12
	System	13 Sep 2020 00:38:12

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-12T18:35:07', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '1b3aea9e-866c-4028-90a8-98a5fe54a2ef' User entered '12 Sep 2020 18:35'	System	13 Sep 2020 00:38:12
	System	13 Sep 2020 00:38:12

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 6'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:58:29', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0de0dd92-055d-43dc-95b0-d0677db0b73e' User entered 'None (0)'	System	14 Sep 2020 01:59:01
	System	14 Sep 2020 01:59:01

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:58:32', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0de0dd92-055d-43dc-95b0-d0677db0b73e' User entered 'None (0)'	System	14 Sep 2020 01:59:01
	System	14 Sep 2020 01:59:01

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:58:36', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0de0dd92-055d-43dc-95b0-d0677db0b73e' User entered 'None (0)'	System	14 Sep 2020 01:59:01
	System	14 Sep 2020 01:59:01

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:58:39', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0de0dd92-055d-43dc-95b0-d0677db0b73e' User entered 'None (0)'	System	14 Sep 2020 01:59:01
	System	14 Sep 2020 01:59:01

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:58:42', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0de0dd92-055d-43dc-95b0-d0677db0b73e' User entered 'None (0)'	System	14 Sep 2020 01:59:01
	System	14 Sep 2020 01:59:01

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:58:45', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0de0dd92-055d-43dc-95b0-d0677db0b73e' User entered 'None (0)'	System	14 Sep 2020 01:59:01
	System	14 Sep 2020 01:59:01

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:58:54', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0de0dd92-055d-43dc-95b0-d0677db0b73e' User entered 'No (N)'	System	14 Sep 2020 01:59:01
	System	14 Sep 2020 01:59:01

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-13T19:58:58', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0de0dd92-055d-43dc-95b0-d0677db0b73e' User entered '13 Sep 2020 19:58'	System	14 Sep 2020 01:59:01
	System	14 Sep 2020 01:59:01

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 7'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:29', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c69840ae-a8a3-444b-afcc-d8622bfa3989' User entered 'None (0)'	System	15 Sep 2020 05:51:57
	System	15 Sep 2020 05:51:57

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:32', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c69840ae-a8a3-444b-afcc-d8622bfa3989' User entered 'None (0)'	System	15 Sep 2020 05:51:57
	System	15 Sep 2020 05:51:57

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:36', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c69840ae-a8a3-444b-afcc-d8622bfa3989' User entered 'None (0)'	System	15 Sep 2020 05:51:57
	System	15 Sep 2020 05:51:57

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:38', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c69840ae-a8a3-444b-afcc-d8622bfa3989' User entered 'None (0)'	System	15 Sep 2020 05:51:57
	System	15 Sep 2020 05:51:57

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:43', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c69840ae-a8a3-444b-afcc-d8622bfa3989' User entered 'None (0)'	System	15 Sep 2020 05:51:57
	System	15 Sep 2020 05:51:57

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:45', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c69840ae-a8a3-444b-afcc-d8622bfa3989' User entered 'None (0)'	System	15 Sep 2020 05:51:57
	System	15 Sep 2020 05:51:57

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:50', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c69840ae-a8a3-444b-afcc-d8622bfa3989'	System	15 Sep 2020 05:51:57
User entered 'No (N)'	System	15 Sep 2020 05:51:57

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-09-15T00:51:53', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c69840ae-a8a3-444b-afcc-d8622bfa3989' User entered '15 Sep 2020 00:51'	System	15 Sep 2020 05:51:57
	System	15 Sep 2020 05:51:57

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:04:24

US3912121

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	15 Sep 2020 18:37:25

US3912121

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '15 Sep 2020'	Amy Collins (b) (4)	15 Sep 2020 18:37:25

US3912121

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Contact Made (CONTACT MADE)'	Amy Collins (b) (4)	15 Sep 2020 18:37:25

US3912121

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	15 Sep 2020 18:37:25

US3912121

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	15 Sep 2020 18:37:31

US3912121

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'I'	System	15 Sep 2020 18:37:31

US3912121

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	22 Sep 2020 20:34:03

US3912121

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '22 Sep 2020'	Amy Collins (b) (4)	22 Sep 2020 20:34:03

US3912121

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Contact Made (CONTACT MADE)'	Amy Collins (b) (4)	22 Sep 2020 20:34:03

US3912121

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	22 Sep 2020 20:34:03

US3912121

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	22 Sep 2020 20:34:13

US3912121

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'I'	System	22 Sep 2020 20:34:13

US3912121

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	29 Sep 2020 23:23:40

US3912121

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '29 Sep 2020'	(b) (4) Monique Gawlik (b) (4)	29 Sep 2020 23:23:40

US3912121

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Monique Gawlik (b) (4)	29 Sep 2020 23:23:40

US3912121

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	(b) (4)	29 Sep 2020 23:23:40
	Monique Gawlik (b) (4)	

US3912121

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	(b) (4) Monique Gawlik (b) (4)	29 Sep 2020 23:23:46

US3912121

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'I'	System	29 Sep 2020 23:23:46

US3912121

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	06 Oct 2020 16:04:06

US3912121

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '06 Oct 2020'	Amy Collins (b) (4)	06 Oct 2020 16:04:06

US3912121

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[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 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Clinic (Clinic)'	Amy Collins (b) (4)	06 Oct 2020 16:04:06

US3912121

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'VISIT2'	System	06 Oct 2020 16:04:06

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User accepted default value 'Pre-Dose (PREDOSE)'	Amy Collins (b) (4) (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '06 Oct 2020'	Amy Collins (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '09:16'	Amy Collins (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered '06 Oct 2020 09:16'	System	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '36.3' C	Amy Collins (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Oral (Oral)'	Amy Collins (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '50'	Amy Collins (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'bpm'	System	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '14'	Amy Collins (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'breaths/min'	System	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '133'	Amy Collins (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'mmHg'	System	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '81'	Amy Collins (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'mmHg'	System	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User accepted default value 'Post-Dose (POSTDOSE)'	Amy Collins (b) (4) (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
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	06 Oct 2020 23:35:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Timothy Vachris (b) (4)	06 Oct 2020 23:35:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	06 Oct 2020 16:05:05
	Amy Collins (b) (4)	06 Oct 2020 16:05:05
	(b) (4)	

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Timothy Vachris (b) (4)	06 Oct 2020 23:35:20
User entered empty.	(b) (4)	
	Amy Collins (b) (4)	06 Oct 2020 16:05:05
	(b) (4)	

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '11:50' reason for change: Data Entry Error	(b) (4)	
	Timothy Vachris (b) (4)	06 Oct 2020 23:35:20
User entered empty.	(b) (4)	
	Amy Collins (b) (4)	06 Oct 2020 16:05:05
	(b) (4)	

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered '06 Oct 2020 11:50'	System	06 Oct 2020 23:35:20
User entered empty.	System	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	06 Oct 2020 23:36:00
data change (Site from System).		06 Oct 2020 23:36:00
User entered '36.7' C reason for change: Data Entry Error	Timothy Vachris (b) (4)	06 Oct 2020 23:36:00
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	06 Oct 2020 23:35:20
	Amy Collins (b) (4)	06 Oct 2020 16:05:05
	(b) (4)	

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Oral (Oral)' reason for change: Data Entry Error	Timothy Vachris (b) (4)	06 Oct 2020 23:36:00
User entered empty.	Amy Collins (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	06 Oct 2020 23:36:00
data change (Site from System).		06 Oct 2020 23:36:00
User entered '54' reason for change: Data Entry Error	Timothy Vachris (b) (4)	06 Oct 2020 23:36:00
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	06 Oct 2020 23:35:20
	Amy Collins (b) (4)	06 Oct 2020 16:05:05
	(b) (4)	

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'bpm'	System	06 Oct 2020 23:36:00
User entered empty.	System	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Oct 2020 23:36:00
Query 'Data is required. Please provide.' answered by System	System	06 Oct 2020 23:36:00
data change (Site from System).		
User entered '15' reason for change: Data Entry	Timothy Vachris (b) (4)	06 Oct 2020 23:36:00
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Oct 2020 23:35:20
User entered empty.	Amy Collins (b) (4)	06 Oct 2020 16:05:05
	(b) (4)	

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'breaths/min'	System	06 Oct 2020 23:36:00
User entered empty.	System	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Oct 2020 23:36:00
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Oct 2020 23:36:00
User entered '119' reason for change: Data Entry Error	Timothy Vachris (b) (4)	06 Oct 2020 23:36:00
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Oct 2020 23:35:20
User entered empty.	Amy Collins (b) (4)	06 Oct 2020 16:05:05
	(b) (4)	

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'mmHg'	System	06 Oct 2020 23:36:00
User entered empty.	System	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Oct 2020 23:36:00
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	06 Oct 2020 23:36:00
User entered '80' reason for change: Data Entry Error	Timothy Vachris (b) (4)	06 Oct 2020 23:36:00
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	06 Oct 2020 23:35:20
User entered empty.	Amy Collins (b) (4)	06 Oct 2020 16:05:05
	(b) (4)	

US3912121

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'mmHg'	System	06 Oct 2020 23:36:00
User entered empty.	System	06 Oct 2020 16:05:05

US3912121

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	06 Oct 2020 16:05:16

US3912121

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '06 Oct 2020'	Amy Collins (b) (4)	06 Oct 2020 16:05:16

US3912121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	06 Oct 2020 16:06:26

US3912121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	06 Oct 2020 16:06:26

US3912121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

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 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	06 Oct 2020 16:06:26

US3912121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 16:06:26

US3912121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '06 Oct 2020'	Amy Collins (b) (4)	06 Oct 2020 16:06:26

US3912121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '10:55'	Amy Collins (b) (4)	06 Oct 2020 16:06:26

US3912121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered '06 Oct 2020 10:55'	System	06 Oct 2020 16:06:26

US3912121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Left Arm (LEFT ARM)'	Amy Collins (b) (4)	06 Oct 2020 16:06:26

US3912121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'ONCE'	System	06 Oct 2020 16:06:26

US3912121

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 16:06:26

US3912121

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	06 Oct 2020 16:07:11

US3912121

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '06 Oct 2020'	Amy Collins (b) (4)	06 Oct 2020 16:07:11

US3912121

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '10:09'	Amy Collins (b) (4)	06 Oct 2020 16:07:11

US3912121

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered '06 Oct 2020 10:09'	System	06 Oct 2020 16:07:11

US3912121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:17:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '06 Oct 2020'	Amy Collins (b) (4)	06 Oct 2020 16:07:33

US3912121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amy Collins (b) (4) (b) (4)	06 Oct 2020 16:07:33

US3912121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	06 Oct 2020 16:07:33

US3912121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '10:18'	Amy Collins (b) (4)	06 Oct 2020 16:07:33

US3912121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:17:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered '06 Oct 2020 10:18'	System	06 Oct 2020 16:07:33

US3912121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amy Collins (b) (4) (b) (4)	06 Oct 2020 16:07:33

US3912121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Amy Collins (b) (4)	06 Oct 2020 16:07:33

US3912121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:58

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	06 Oct 2020 16:07:33

US3912121

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:17:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered empty.	System	06 Oct 2020 16:07:33

US3912121

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Timothy Vachris (b) (4)	06 Oct 2020 23:36:39

US3912121

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'I'	System	06 Oct 2020 23:36:39

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:52:30', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd1df9d7c-b8a4-4b4e-961a-27509b18ba92'	System	06 Oct 2020 16:52:54
User entered 'Yes (Y)'	System	06 Oct 2020 16:52:54

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:52:39', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd1df9d7c-b8a4-4b4e-961a-27509b18ba92'	System	06 Oct 2020 16:52:54
User entered '98.0'	System	06 Oct 2020 16:52:54

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:52:47', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd1df9d7c-b8a4-4b4e-961a-27509b18ba92'	System	06 Oct 2020 16:52:54
User entered 'No (N)'	System	06 Oct 2020 16:52:54

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:52:52', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd1df9d7c-b8a4-4b4e-961a-27509b18ba92'	System	06 Oct 2020 16:52:54
User entered '06 Oct 2020 11:52'	System	06 Oct 2020 16:52:54

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '06 Oct 2020 11:15'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '06 Oct 2020 13:45'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:20:51', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97f31dd3-6e1a-4b1b-b14e-bf989f4eeb30' User entered 'Yes (Y)'	System	07 Oct 2020 01:21:35
	System	07 Oct 2020 01:21:35

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:21:05', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97f31dd3-6e1a-4b1b-b14e-bf989f4eeb30' User entered '97.6'	System	07 Oct 2020 01:21:35
	System	07 Oct 2020 01:21:35

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:21:15', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97f31dd3-6e1a-4b1b-b14e-bf989f4eeb30'	System	07 Oct 2020 01:21:35
User entered 'No (N)'	System	07 Oct 2020 01:21:35

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:21:22', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '97f31dd3-6e1a-4b1b-b14e-bf989f4eeb30' User entered '06 Oct 2020 20:21'	System	07 Oct 2020 01:21:35
	System	07 Oct 2020 01:21:35

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '06 Oct 2020 14:40'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 2'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:07:04', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f8fad2b0-1687-4f8a-8701-778d5f502b7a' User entered 'Yes (Y)'	System	08 Oct 2020 02:07:25
	System	08 Oct 2020 02:07:25

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:07:13', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f8fad2b0-1687-4f8a-8701-778d5f502b7a' User entered '98.4'	System	08 Oct 2020 02:07:25
	System	08 Oct 2020 02:07:25

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:07:18', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f8fad2b0-1687-4f8a-8701-778d5f502b7a'	System	08 Oct 2020 02:07:25
User entered 'No (N)'	System	08 Oct 2020 02:07:25

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:07:22', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f8fad2b0-1687-4f8a-8701-778d5f502b7a' User entered '07 Oct 2020 21:07'	System	08 Oct 2020 02:07:25
	System	08 Oct 2020 02:07:25

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 3'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:12:37', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'b93d86e8-afb7-41bb-9fc9-7ec3e15e2166'	System	09 Oct 2020 01:12:56
User entered 'Yes (Y)'	System	09 Oct 2020 01:12:56

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:12:45', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'b93d86e8-afb7-41bb-9fc9-7ec3e15e2166'	System	09 Oct 2020 01:12:56
User entered '98.1'	System	09 Oct 2020 01:12:56

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:12:51', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'b93d86e8-afb7-41bb-9fc9-7ec3e15e2166'	System	09 Oct 2020 01:12:56
User entered 'No (N)'	System	09 Oct 2020 01:12:56

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:12:55', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'b93d86e8-afb7-41bb-9fc9-7ec3e15e2166'	System	09 Oct 2020 01:12:56
User entered '08 Oct 2020 20:12'	System	09 Oct 2020 01:12:56

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 4'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:16:59', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'af704afd-01bc-48de-8212-54b8ceea0ce7' User entered 'Yes (Y)'	System	10 Oct 2020 02:17:23
	System	10 Oct 2020 02:17:23

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:17:06', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'af704afd-01bc-48de-8212-54b8ceea0ce7' User entered '98.1'	System	10 Oct 2020 02:17:23
	System	10 Oct 2020 02:17:23

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:17:13', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'af704afd-01bc-48de-8212-54b8ceea0ce7' User entered 'No (N)'	System	10 Oct 2020 02:17:23
	System	10 Oct 2020 02:17:23

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:17:21', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'af704afd-01bc-48de-8212-54b8ceea0ce7' User entered '09 Oct 2020 21:17'	System	10 Oct 2020 02:17:23
	System	10 Oct 2020 02:17:23

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 5'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:24:28', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6674aa95-1552-42d7-8234-72702434a2b6'	System	11 Oct 2020 01:24:50
User entered 'Yes (Y)'	System	11 Oct 2020 01:24:50

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:24:37', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6674aa95-1552-42d7-8234-72702434a2b6'	System	11 Oct 2020 01:24:50
User entered '97.8'	System	11 Oct 2020 01:24:50

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:24:44', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6674aa95-1552-42d7-8234-72702434a2b6'	System	11 Oct 2020 01:24:50
User entered 'No (N)'	System	11 Oct 2020 01:24:50

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:24:48', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6674aa95-1552-42d7-8234-72702434a2b6' User entered '10 Oct 2020 20:24'	System	11 Oct 2020 01:24:50
	System	11 Oct 2020 01:24:50

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 6'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:12:01', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'adc7ff13-26ab-4ab3-9719-3854926dc680' User entered 'Yes (Y)'	System	12 Oct 2020 02:12:26
	System	12 Oct 2020 02:12:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:12:12', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'adc7ff13-26ab-4ab3-9719-3854926dc680' User entered '97.8'	System	12 Oct 2020 02:12:26
	System	12 Oct 2020 02:12:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:12:20', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'adc7ff13-26ab-4ab3-9719-3854926dc680'	System	12 Oct 2020 02:12:26
User entered 'No (N)'	System	12 Oct 2020 02:12:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:12:23', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'adc7ff13-26ab-4ab3-9719-3854926dc680'	System	12 Oct 2020 02:12:26
User entered '11 Oct 2020 21:12'	System	12 Oct 2020 02:12:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 7'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:09:37', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '2a3b9b90-b943-4826-b6d8-82178183fe02'	System	13 Oct 2020 02:09:58
User entered 'Yes (Y)'	System	13 Oct 2020 02:09:58

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:09:45', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '2a3b9b90-b943-4826-b6d8-82178183fe02'	System	13 Oct 2020 02:09:58
User entered '97.6'	System	13 Oct 2020 02:09:58

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:09:52', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '2a3b9b90-b943-4826-b6d8-82178183fe02'	System	13 Oct 2020 02:09:58
User entered 'No (N)'	System	13 Oct 2020 02:09:58

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:09:56', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '2a3b9b90-b943-4826-b6d8-82178183fe02'	System	13 Oct 2020 02:09:58
User entered '12 Oct 2020 21:09'	System	13 Oct 2020 02:09:58

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:53:14', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6c15e3b1-cd7a-45d7-8c85-59fdf47c1a57'	System	06 Oct 2020 16:53:58
User entered 'None (1)'	System	06 Oct 2020 16:53:58

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:53:19', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6c15e3b1-cd7a-45d7-8c85-59fdf47c1a57'	System	06 Oct 2020 16:53:58
User entered 'No (N)'	System	06 Oct 2020 16:53:58

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:53:22', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6c15e3b1-cd7a-45d7-8c85-59fdf47c1a57'	System	06 Oct 2020 16:53:58
User entered 'No (N)'	System	06 Oct 2020 16:53:58

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:53:35', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6c15e3b1-cd7a-45d7-8c85-59fdf47c1a57'	System	06 Oct 2020 16:53:58
User entered 'None (1)'	System	06 Oct 2020 16:53:58

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:53:39', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6c15e3b1-cd7a-45d7-8c85-59fdf47c1a57' User entered '06 Oct 2020 11:53'	System	06 Oct 2020 16:53:58
	System	06 Oct 2020 16:53:58

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '06 Oct 2020 11:15'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '06 Oct 2020 13:45'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:21:34', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6198a4d0-ed96-4aa1-bd5e-35d79fe704ee' User entered 'None (1)'	System	07 Oct 2020 01:22:17
	System	07 Oct 2020 01:22:17

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:21:52', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6198a4d0-ed96-4aa1-bd5e-35d79fe704ee' User entered 'No (N)'	System	07 Oct 2020 01:22:17
	System	07 Oct 2020 01:22:17

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:21:59', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6198a4d0-ed96-4aa1-bd5e-35d79fe704ee' User entered 'No (N)'	System	07 Oct 2020 01:22:17
	System	07 Oct 2020 01:22:17

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:22:11', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6198a4d0-ed96-4aa1-bd5e-35d79fe704ee' User entered 'None (1)'	System	07 Oct 2020 01:22:17
	System	07 Oct 2020 01:22:17

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:22:15', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '6198a4d0-ed96-4aa1-bd5e-35d79fe704ee' User entered '06 Oct 2020 20:22'	System	07 Oct 2020 01:22:17
	System	07 Oct 2020 01:22:17

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '06 Oct 2020 14:40'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 2'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:07:32', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'eaf7b0da-5029-493b-a336-908a303ffca0' User entered 'None (1)'	System	08 Oct 2020 02:08:01
	System	08 Oct 2020 02:08:01

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:07:36', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'eaf7b0da-5029-493b-a336-908a303ffca0' User entered 'No (N)'	System	08 Oct 2020 02:08:01
	System	08 Oct 2020 02:08:01

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:07:50', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'eaf7b0da-5029-493b-a336-908a303ffca0' User entered 'No (N)'	System	08 Oct 2020 02:08:01
	System	08 Oct 2020 02:08:01

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:07:55', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'eaf7b0da-5029-493b-a336-908a303ffca0' User entered 'None (1)'	System	08 Oct 2020 02:08:01
	System	08 Oct 2020 02:08:01

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:07:59', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'eaf7b0da-5029-493b-a336-908a303ffca0' User entered '07 Oct 2020 21:07'	System	08 Oct 2020 02:08:01
	System	08 Oct 2020 02:08:01

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 3'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:13:01', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '110b45da-8921-4575-9a45-162945281c4c'	System	09 Oct 2020 01:13:45
User entered 'None (1)'	System	09 Oct 2020 01:13:45

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:13:06', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '110b45da-8921-4575-9a45-162945281c4c'	System	09 Oct 2020 01:13:45
User entered 'No (N)'	System	09 Oct 2020 01:13:45

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:13:20', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '110b45da-8921-4575-9a45-162945281c4c'	System	09 Oct 2020 01:13:45
User entered 'No (N)'	System	09 Oct 2020 01:13:45

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:13:35', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '110b45da-8921-4575-9a45-162945281c4c'	System	09 Oct 2020 01:13:45
User entered 'None (1)'	System	09 Oct 2020 01:13:45

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:13:41', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '110b45da-8921-4575-9a45-162945281c4c' User entered '08 Oct 2020 20:13'	System	09 Oct 2020 01:13:45
	System	09 Oct 2020 01:13:45

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 4'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:17:33', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'acd2b3c5-1c23-4437-966e-b46937a626c9' User entered 'None (1)'	System	10 Oct 2020 02:18:10
	System	10 Oct 2020 02:18:10

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:17:41', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'acd2b3c5-1c23-4437-966e-b46937a626c9' User entered 'No (N)'	System	10 Oct 2020 02:18:10
	System	10 Oct 2020 02:18:10

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:17:51', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'acd2b3c5-1c23-4437-966e-b46937a626c9' User entered 'No (N)'	System	10 Oct 2020 02:18:10
	System	10 Oct 2020 02:18:10

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:18:01', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'acd2b3c5-1c23-4437-966e-b46937a626c9' User entered 'None (1)'	System	10 Oct 2020 02:18:10
	System	10 Oct 2020 02:18:10

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:18:08', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'acd2b3c5-1c23-4437-966e-b46937a626c9' User entered '09 Oct 2020 21:18'	System	10 Oct 2020 02:18:10
	System	10 Oct 2020 02:18:10

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 5'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:24:53', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f73dc7b3-2507-4919-8a80-b0c3c74ff80d' User entered 'None (1)'	System	11 Oct 2020 01:25:13
	System	11 Oct 2020 01:25:13

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:24:56', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f73dc7b3-2507-4919-8a80-b0c3c74ff80d' User entered 'No (N)'	System	11 Oct 2020 01:25:13
	System	11 Oct 2020 01:25:13

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:25:04', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f73dc7b3-2507-4919-8a80-b0c3c74ff80d' User entered 'No (N)'	System	11 Oct 2020 01:25:13
	System	11 Oct 2020 01:25:13

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:25:09', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f73dc7b3-2507-4919-8a80-b0c3c74ff80d'	System	11 Oct 2020 01:25:13
User entered 'None (1)'	System	11 Oct 2020 01:25:13

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:25:12', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'f73dc7b3-2507-4919-8a80-b0c3c74ff80d' User entered '10 Oct 2020 20:25'	System	11 Oct 2020 01:25:13
	System	11 Oct 2020 01:25:13

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 6'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:12:29', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '85f7c366-ce4d-4878-97ba-2859574786dc' User entered 'None (1)'	System	12 Oct 2020 02:12:54
	System	12 Oct 2020 02:12:54

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:12:33', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '85f7c366-ce4d-4878-97ba-2859574786dc' User entered 'No (N)'	System	12 Oct 2020 02:12:54
	System	12 Oct 2020 02:12:54

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:12:41', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '85f7c366-ce4d-4878-97ba-2859574786dc' User entered 'No (N)'	System	12 Oct 2020 02:12:54
	System	12 Oct 2020 02:12:54

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:12:48', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '85f7c366-ce4d-4878-97ba-2859574786dc' User entered 'None (1)'	System	12 Oct 2020 02:12:54
	System	12 Oct 2020 02:12:54

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:12:51', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '85f7c366-ce4d-4878-97ba-2859574786dc' User entered '11 Oct 2020 21:12'	System	12 Oct 2020 02:12:54
	System	12 Oct 2020 02:12:54

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 7'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:10:03', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '28bcd4ba-eb9b-4322-8a7a-3826a4f9b293'	System	13 Oct 2020 02:10:46
User entered 'None (1)'	System	13 Oct 2020 02:10:46

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:10:18', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '28bcd4ba-eb9b-4322-8a7a-3826a4f9b293'	System	13 Oct 2020 02:10:46
User entered 'No (N)'	System	13 Oct 2020 02:10:46

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:10:29', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '28bcd4ba-eb9b-4322-8a7a-3826a4f9b293'	System	13 Oct 2020 02:10:46
User entered 'No (N)'	System	13 Oct 2020 02:10:46

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:10:39', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '28bcd4ba-eb9b-4322-8a7a-3826a4f9b293'	System	13 Oct 2020 02:10:46
User entered 'None (1)'	System	13 Oct 2020 02:10:46

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:10:43', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '28bcd4ba-eb9b-4322-8a7a-3826a4f9b293'	System	13 Oct 2020 02:10:46
User entered '12 Oct 2020 21:10'	System	13 Oct 2020 02:10:46

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:53:47', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0227cdb2-9e43-4af9-b0b1-e83b6af74d21' User entered 'None (0)'	System	06 Oct 2020 16:54:18
	System	06 Oct 2020 16:54:18

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:53:51', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0227cdb2-9e43-4af9-b0b1-e83b6af74d21' User entered 'None (0)'	System	06 Oct 2020 16:54:18
	System	06 Oct 2020 16:54:18

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:53:54', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0227cdb2-9e43-4af9-b0b1-e83b6af74d21' User entered 'None (0)'	System	06 Oct 2020 16:54:18
	System	06 Oct 2020 16:54:18

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:53:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0227cdb2-9e43-4af9-b0b1-e83b6af74d21' User entered 'None (0)'	System	06 Oct 2020 16:54:18
	System	06 Oct 2020 16:54:18

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:54:00', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0227cdb2-9e43-4af9-b0b1-e83b6af74d21' User entered 'None (0)'	System	06 Oct 2020 16:54:18
	System	06 Oct 2020 16:54:18

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:54:03', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0227cdb2-9e43-4af9-b0b1-e83b6af74d21' User entered 'None (0)'	System	06 Oct 2020 16:54:18
	System	06 Oct 2020 16:54:18

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:54:09', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0227cdb2-9e43-4af9-b0b1-e83b6af74d21' User entered 'No (N)'	System	06 Oct 2020 16:54:18
	System	06 Oct 2020 16:54:18

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T11:54:15', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '0227cdb2-9e43-4af9-b0b1-e83b6af74d21' User entered '06 Oct 2020 11:54'	System	06 Oct 2020 16:54:18
	System	06 Oct 2020 16:54:18

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '06 Oct 2020 11:15'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '06 Oct 2020 13:45'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:22:28', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd1b9a29b-810b-470d-862f-3cadab155ee3' User entered 'None (0)'	System	07 Oct 2020 01:23:04
	System	07 Oct 2020 01:23:04

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:22:32', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd1b9a29b-810b-470d-862f-3cadab155ee3' User entered 'None (0)'	System	07 Oct 2020 01:23:04
	System	07 Oct 2020 01:23:04

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:22:37', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd1b9a29b-810b-470d-862f-3cadab155ee3' User entered 'None (0)'	System	07 Oct 2020 01:23:04
	System	07 Oct 2020 01:23:04

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:22:41', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd1b9a29b-810b-470d-862f-3cadab155ee3' User entered 'None (0)'	System	07 Oct 2020 01:23:04
	System	07 Oct 2020 01:23:04

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:22:44', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd1b9a29b-810b-470d-862f-3cadab155ee3' User entered 'None (0)'	System	07 Oct 2020 01:23:04
	System	07 Oct 2020 01:23:04

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:22:48', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd1b9a29b-810b-470d-862f-3cadab155ee3' User entered 'None (0)'	System	07 Oct 2020 01:23:04
	System	07 Oct 2020 01:23:04

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:22:55', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd1b9a29b-810b-470d-862f-3cadab155ee3' User entered 'No (N)'	System	07 Oct 2020 01:23:04
	System	07 Oct 2020 01:23:04

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-06T20:22:59', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd1b9a29b-810b-470d-862f-3cadab155ee3' User entered '06 Oct 2020 20:22'	System	07 Oct 2020 01:23:04
	System	07 Oct 2020 01:23:04

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '06 Oct 2020 14:40'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 2'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:08:07', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '720c6dce-04b1-461e-9cb7-e04626db8255' User entered 'None (0)'	System	08 Oct 2020 02:08:53
	System	08 Oct 2020 02:08:53

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:08:22', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '720c6dce-04b1-461e-9cb7-e04626db8255'	System	08 Oct 2020 02:08:53
User entered 'No interference with activity (1)'	System	08 Oct 2020 02:08:53

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:08:27', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '720c6dce-04b1-461e-9cb7-e04626db8255' User entered 'None (0)'	System	08 Oct 2020 02:08:53
	System	08 Oct 2020 02:08:53

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:08:33', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '720c6dce-04b1-461e-9cb7-e04626db8255' User entered 'None (0)'	System	08 Oct 2020 02:08:53
	System	08 Oct 2020 02:08:53

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:08:37', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '720c6dce-04b1-461e-9cb7-e04626db8255' User entered 'None (0)'	System	08 Oct 2020 02:08:53
	System	08 Oct 2020 02:08:53

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:08:40', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '720c6dce-04b1-461e-9cb7-e04626db8255' User entered 'None (0)'	System	08 Oct 2020 02:08:53
	System	08 Oct 2020 02:08:53

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:08:47', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '720c6dce-04b1-461e-9cb7-e04626db8255'	System	08 Oct 2020 02:08:53
User entered 'No (N)'	System	08 Oct 2020 02:08:53

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-07T21:08:50', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '720c6dce-04b1-461e-9cb7-e04626db8255' User entered '07 Oct 2020 21:08'	System	08 Oct 2020 02:08:53
	System	08 Oct 2020 02:08:53

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 3'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:13:47', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'aa91ff1e-d7a2-48d1-86aa-fe178f48d65c' User entered 'None (0)'	System	09 Oct 2020 01:14:20
	System	09 Oct 2020 01:14:20

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:13:51', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'aa91ff1e-d7a2-48d1-86aa-fe178f48d65c' User entered 'None (0)'	System	09 Oct 2020 01:14:20
	System	09 Oct 2020 01:14:20

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:13:56', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'aa91ff1e-d7a2-48d1-86aa-fe178f48d65c' User entered 'None (0)'	System	09 Oct 2020 01:14:20
	System	09 Oct 2020 01:14:20

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:14:01', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'aa91ff1e-d7a2-48d1-86aa-fe178f48d65c' User entered 'None (0)'	System	09 Oct 2020 01:14:20
	System	09 Oct 2020 01:14:20

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:14:04', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'aa91ff1e-d7a2-48d1-86aa-fe178f48d65c' User entered 'None (0)'	System	09 Oct 2020 01:14:20
	System	09 Oct 2020 01:14:20

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:14:08', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'aa91ff1e-d7a2-48d1-86aa-fe178f48d65c' User entered 'None (0)'	System	09 Oct 2020 01:14:20
	System	09 Oct 2020 01:14:20

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:14:14', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'aa91ff1e-d7a2-48d1-86aa-fe178f48d65c' User entered 'No (N)'	System	09 Oct 2020 01:14:20
	System	09 Oct 2020 01:14:20

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-08T20:14:18', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'aa91ff1e-d7a2-48d1-86aa-fe178f48d65c' User entered '08 Oct 2020 20:14'	System	09 Oct 2020 01:14:20
	System	09 Oct 2020 01:14:20

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 4'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:18:17', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '36c01be6-7eb4-4791-ade6-c01ed69a1f16' User entered 'None (0)'	System	10 Oct 2020 02:19:10
	System	10 Oct 2020 02:19:10

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:18:26', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '36c01be6-7eb4-4791-ade6-c01ed69a1f16' User entered 'None (0)'	System	10 Oct 2020 02:19:10
	System	10 Oct 2020 02:19:10

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:18:30', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '36c01be6-7eb4-4791-ade6-c01ed69a1f16' User entered 'None (0)'	System	10 Oct 2020 02:19:10
	System	10 Oct 2020 02:19:10

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:18:35', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '36c01be6-7eb4-4791-ade6-c01ed69a1f16' User entered 'None (0)'	System	10 Oct 2020 02:19:10
	System	10 Oct 2020 02:19:10

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:18:41', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '36c01be6-7eb4-4791-ade6-c01ed69a1f16' User entered 'None (0)'	System	10 Oct 2020 02:19:10
	System	10 Oct 2020 02:19:10

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:18:50', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '36c01be6-7eb4-4791-ade6-c01ed69a1f16' User entered 'None (0)'	System	10 Oct 2020 02:19:10
	System	10 Oct 2020 02:19:10

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:19:03', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '36c01be6-7eb4-4791-ade6-c01ed69a1f16' User entered 'No (N)'	System	10 Oct 2020 02:19:10
	System	10 Oct 2020 02:19:10

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-09T21:19:06', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '36c01be6-7eb4-4791-ade6-c01ed69a1f16' User entered '09 Oct 2020 21:19'	System	10 Oct 2020 02:19:10
	System	10 Oct 2020 02:19:10

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 5'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:25:16', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e2864fd7-74d1-4dd8-831c-b5502a491b5d' User entered 'None (0)'	System	11 Oct 2020 01:25:46
	System	11 Oct 2020 01:25:46

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:25:21', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e2864fd7-74d1-4dd8-831c-b5502a491b5d' User entered 'None (0)'	System	11 Oct 2020 01:25:46
	System	11 Oct 2020 01:25:46

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:25:25', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e2864fd7-74d1-4dd8-831c-b5502a491b5d' User entered 'None (0)'	System	11 Oct 2020 01:25:46
	System	11 Oct 2020 01:25:46

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:25:29', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e2864fd7-74d1-4dd8-831c-b5502a491b5d' User entered 'None (0)'	System	11 Oct 2020 01:25:46
	System	11 Oct 2020 01:25:46

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:25:33', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e2864fd7-74d1-4dd8-831c-b5502a491b5d' User entered 'None (0)'	System	11 Oct 2020 01:25:46
	System	11 Oct 2020 01:25:46

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:25:35', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e2864fd7-74d1-4dd8-831c-b5502a491b5d' User entered 'None (0)'	System	11 Oct 2020 01:25:46
	System	11 Oct 2020 01:25:46

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:25:41', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e2864fd7-74d1-4dd8-831c-b5502a491b5d' User entered 'No (N)'	System	11 Oct 2020 01:25:46
	System	11 Oct 2020 01:25:46

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-10T20:25:43', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'e2864fd7-74d1-4dd8-831c-b5502a491b5d' User entered '10 Oct 2020 20:25'	System	11 Oct 2020 01:25:46
	System	11 Oct 2020 01:25:46

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 6'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:12:58', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'bc8e8505-c118-4874-b954-97287f74636c' User entered 'None (0)'	System	12 Oct 2020 02:13:35
	System	12 Oct 2020 02:13:35

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:13:01', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'bc8e8505-c118-4874-b954-97287f74636c' User entered 'None (0)'	System	12 Oct 2020 02:13:35
	System	12 Oct 2020 02:13:35

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:13:08', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'bc8e8505-c118-4874-b954-97287f74636c' User entered 'None (0)'	System	12 Oct 2020 02:13:35
	System	12 Oct 2020 02:13:35

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:13:11', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'bc8e8505-c118-4874-b954-97287f74636c' User entered 'None (0)'	System	12 Oct 2020 02:13:35
	System	12 Oct 2020 02:13:35

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:13:14', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'bc8e8505-c118-4874-b954-97287f74636c' User entered 'None (0)'	System	12 Oct 2020 02:13:35
	System	12 Oct 2020 02:13:35

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:13:17', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'bc8e8505-c118-4874-b954-97287f74636c' User entered 'None (0)'	System	12 Oct 2020 02:13:35
	System	12 Oct 2020 02:13:35

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:13:29', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'bc8e8505-c118-4874-b954-97287f74636c' User entered 'No (N)'	System	12 Oct 2020 02:13:35
	System	12 Oct 2020 02:13:35

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-11T21:13:32', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'bc8e8505-c118-4874-b954-97287f74636c'	System	12 Oct 2020 02:13:35
User entered '11 Oct 2020 21:13'	System	12 Oct 2020 02:13:35

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	06 Oct 2020 16:06:26
User entered 'Day 7'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:10:49', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c3beebf9-2613-461b-b22a-e880c7da5620' User entered 'None (0)'	System	13 Oct 2020 02:11:17
	System	13 Oct 2020 02:11:17

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:10:52', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c3beebf9-2613-461b-b22a-e880c7da5620' User entered 'None (0)'	System	13 Oct 2020 02:11:17
	System	13 Oct 2020 02:11:17

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:10:56', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c3beebf9-2613-461b-b22a-e880c7da5620' User entered 'None (0)'	System	13 Oct 2020 02:11:17
	System	13 Oct 2020 02:11:17

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:10:59', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c3beebf9-2613-461b-b22a-e880c7da5620' User entered 'None (0)'	System	13 Oct 2020 02:11:17
	System	13 Oct 2020 02:11:17

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:11:01', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c3beebf9-2613-461b-b22a-e880c7da5620' User entered 'None (0)'	System	13 Oct 2020 02:11:17
	System	13 Oct 2020 02:11:17

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:11:04', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c3beebf9-2613-461b-b22a-e880c7da5620' User entered 'None (0)'	System	13 Oct 2020 02:11:17
	System	13 Oct 2020 02:11:17

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:11:11', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c3beebf9-2613-461b-b22a-e880c7da5620' User entered 'No (N)'	System	13 Oct 2020 02:11:17
	System	13 Oct 2020 02:11:17

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-10-12T21:11:14', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'c3beebf9-2613-461b-b22a-e880c7da5620' User entered '12 Oct 2020 21:11'	System	13 Oct 2020 02:11:17
	System	13 Oct 2020 02:11:17

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 16:06:26

US3912121

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:17:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 16:06:26

US3912121

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	13 Oct 2020 21:27:29

US3912121

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '13 Oct 2020'	Amy Collins (b) (4)	13 Oct 2020 21:27:29

US3912121

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Contact Made (CONTACT MADE)'	Amy Collins (b) (4)	13 Oct 2020 21:27:29

US3912121

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Amy Collins (b) (4)	13 Oct 2020 21:27:29

US3912121

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Amy Collins (b) (4)	13 Oct 2020 21:27:34

US3912121

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'I'	System	13 Oct 2020 21:27:34

US3912121

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	20 Oct 2020 16:03:47

US3912121

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '20 Oct 2020'	Sandra Clancy (b) (4)	20 Oct 2020 16:03:47

US3912121

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Contact Made (CONTACT MADE)'	Sandra Clancy (b) (4)	20 Oct 2020 16:03:47

US3912121

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Sandra Clancy (b) (4)	20 Oct 2020 16:03:47

US3912121

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	20 Oct 2020 16:03:51

US3912121

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'I'	System	20 Oct 2020 16:03:51

US3912121

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 03NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 10:43:46
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 03NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' answered with 'Lab collected REQ # 1F623934085' (Site from DM).	Mia Rountree (b) (4) (b) (4)	13 Nov 2020 23:25:21
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 03NOV2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 00:52:10
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:23:41

US3912121

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '28 Oct 2020'	Mia Rountree (b) (4)	28 Oct 2020 16:23:41

US3912121

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Contact Made (CONTACT MADE)'	Mia Rountree (b) (4)	28 Oct 2020 16:23:41

US3912121

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Mia Rountree (b) (4)	28 Oct 2020 16:23:41

US3912121

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Mia Rountree (b) (4)	28 Oct 2020 16:23:48

US3912121

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'I'	System	28 Oct 2020 16:23:48

US3912121

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Mia Rountree (b) (4)	16 Nov 2020 16:05:08

US3912121

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '03 Nov 2020'	Mia Rountree (b) (4)	16 Nov 2020 16:05:08

US3912121

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[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 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Clinic (Clinic)'	Mia Rountree (b) (4)	16 Nov 2020 16:05:08

US3912121

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'VISIT3'	System	16 Nov 2020 16:05:08

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Mia Rountree (b) (4)	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '03 Nov 2020'	Mia Rountree (b) (4)	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '09:19'	Mia Rountree (b) (4)	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered '03 Nov 2020 09:19'	System	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '36.3' C	Mia Rountree (b) (4)	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Oral (Oral)'	Mia Rountree (b) (4)	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Mia Rountree (b) (4)	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Per CDM: Per CCG V2.0 page 53, Pulse < 55 or >100 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 04:38:17
Query 'Per CDM: Per CCG V2.0 page 53, Pulse < 55 or >100 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'Investigator deemed NCS' (Site from DM).	Mia Rountree (b) (4) (b) (4)	25 Nov 2020 16:44:46
User opened query 'Per CDM: Per CCG V2.0 page 53, Pulse < 55 or >100 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 04:40:10
User entered '51'	Mia Rountree (b) (4) (b) (4)	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'bpm'	System	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '14'	Mia Rountree (b) (4)	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'breaths/min'	System	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '133'	Mia Rountree (b) (4)	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'mmHg'	System	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '71'	Mia Rountree (b) (4)	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'mmHg'	System	16 Nov 2020 16:05:56

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40

US3912121

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40

US3912121

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'No (N)'	Mia Rountree (b) (4)	16 Nov 2020 16:06:07

US3912121

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Mia Rountree (b) (4)	16 Nov 2020 16:06:07

US3912121

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Mia Rountree (b) (4)	16 Nov 2020 16:06:26

US3912121

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '03 Nov 2020'	Mia Rountree (b) (4)	16 Nov 2020 16:06:26

US3912121

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '09:35'	Mia Rountree (b) (4)	16 Nov 2020 16:06:26

US3912121

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered '03 Nov 2020 09:35'	System	16 Nov 2020 16:06:26

US3912121

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Mia Rountree (b) (4)	16 Nov 2020 16:06:35

US3912121

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'I'	System	16 Nov 2020 16:06:35

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 64'	System	08 Sep 2020 19:04:24

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-11-10T17:21:45', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd69ef838-f636-4698-ab40-b9e2c2873145'	System	10 Nov 2020 23:22:10
User entered 'No (N)'	System	10 Nov 2020 23:22:10

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-11-10T17:21:55', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd69ef838-f636-4698-ab40-b9e2c2873145'	System	10 Nov 2020 23:22:10
User entered 'No (N)'	System	10 Nov 2020 23:22:10

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-11-10T17:22:01', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'd69ef838-f636-4698-ab40-b9e2c2873145' User entered '10 Nov 2020 17:22:01'	System	10 Nov 2020 23:22:10
	System	10 Nov 2020 23:22:10

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 19:04:24

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered 'Day 71'	System	08 Sep 2020 19:04:24

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-11-17T17:57:35', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '7aa1c80e-0968-4d36-a279-6c9570f84cbf' User entered 'No (N)'	System	17 Nov 2020 23:58:04
	System	17 Nov 2020 23:58:04

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-11-17T17:57:44', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '7aa1c80e-0968-4d36-a279-6c9570f84cbf' User entered 'No (N)'	System	17 Nov 2020 23:58:04
	System	17 Nov 2020 23:58:04

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-11-17T17:58:01', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '7aa1c80e-0968-4d36-a279-6c9570f84cbf' User entered '17 Nov 2020 17:58:01'	System	17 Nov 2020 23:58:04
	System	17 Nov 2020 23:58:04

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 19:04:24

US3912121

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:15:07
Data entry locked.	System	08 Sep 2020 19:04:24
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 19:04:24

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-11-29T19:50:05', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '4611d0b4-a96d-43eb-82a6-4edecbe06a43' User entered 'No (N)'	System	30 Nov 2020 01:50:21
	System	30 Nov 2020 01:50:21

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-11-29T19:50:09', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '4611d0b4-a96d-43eb-82a6-4edecbe06a43' User entered 'No (N)'	System	30 Nov 2020 01:50:21

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-11-29T19:50:19', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '4611d0b4-a96d-43eb-82a6-4edecbe06a43' User entered '29 Nov 2020 19:50:19'	System	30 Nov 2020 01:50:21
	System	30 Nov 2020 01:50:21

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-07T18:54:17', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '3deffe15-4627-43bd-a2e6-0bdb833c5379'	System	08 Dec 2020 00:54:41
User entered 'No (N)'	System	08 Dec 2020 00:54:41

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-07T18:54:28', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '3deffe15-4627-43bd-a2e6-0bdb833c5379'	System	08 Dec 2020 00:54:41
User entered 'No (N)'	System	08 Dec 2020 00:54:41

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-07T18:54:39', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '3deffe15-4627-43bd-a2e6-0bdb833c5379' User entered '07 Dec 2020 18:54:39'	System	08 Dec 2020 00:54:41
	System	08 Dec 2020 00:54:41

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-14T18:26:26', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'efdd7faf-8688-4187-8f99-34c6ed14efa4'	System	15 Dec 2020 00:26:50
User entered 'No (N)'	System	15 Dec 2020 00:26:50

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-14T18:26:34', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'efdd7faf-8688-4187-8f99-34c6ed14efa4'	System	15 Dec 2020 00:26:50
User entered 'No (N)'	System	15 Dec 2020 00:26:50

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-14T18:26:48', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'efdd7faf-8688-4187-8f99-34c6ed14efa4'	System	15 Dec 2020 00:26:50
User entered '14 Dec 2020 18:26:48'	System	15 Dec 2020 00:26:50

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:48:39', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered 'Yes (Y)'	System	18 Dec 2020 09:50:49
	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:48:46', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered 'No (N)'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:48:55', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered 'Yes (Y)'	System	18 Dec 2020 09:50:49
	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered '0'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c'	System	18 Dec 2020 09:50:49
User entered '1'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered '0'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered '0'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered '0'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered '0'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered '0'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered '0'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered '0'	System	18 Dec 2020 09:50:49
	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered '0'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered '0'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered '0'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered '0'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c'	System	18 Dec 2020 09:50:49
User entered '1'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c'	System	18 Dec 2020 09:50:49
User entered '1'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c'	System	18 Dec 2020 09:50:49
User entered '1'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:49:57', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c'	System	18 Dec 2020 09:50:49
User entered '0'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:50:15', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c'	System	18 Dec 2020 09:50:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:50:30', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c'	System	18 Dec 2020 09:50:49
User entered 'No (N)'	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2020-12-18T03:50:39', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '287693a3-8589-4627-8d4b-d284322a821c' User entered '18 Dec 2020 03:50:39'	System	18 Dec 2020 09:50:49
	System	18 Dec 2020 09:50:49

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-04T21:30:13', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'af4b3ec7-e4af-4fc1-860b-da9a48da69ad' User entered 'Yes (Y)'	System	05 Jan 2021 03:31:33
	System	05 Jan 2021 03:31:33

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-04T21:30:20', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'af4b3ec7-e4af-4fc1-860b-da9a48da69ad' User entered 'No (N)'	System	05 Jan 2021 03:31:33

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-04T21:30:27', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'af4b3ec7-e4af-4fc1-860b-da9a48da69ad'	System	05 Jan 2021 03:31:33
User entered 'No (N)'	System	05 Jan 2021 03:31:33

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-04T21:30:39', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'af4b3ec7-e4af-4fc1-860b-da9a48da69ad' User entered 'Yes (Y)'	System	05 Jan 2021 03:31:33
	System	05 Jan 2021 03:31:33

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-04T21:31:10', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'af4b3ec7-e4af-4fc1-860b-da9a48da69ad'	System	05 Jan 2021 03:31:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Jan 2021 03:31:33

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-04T21:31:21', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'af4b3ec7-e4af-4fc1-860b-da9a48da69ad' User entered '04 Jan 2021 21:31:21'	System	05 Jan 2021 03:31:33

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-11T20:12:41', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '266d83cc-a7b0-4e15-98a4-f7eb899598d8' User entered 'No (N)'	System	12 Jan 2021 02:12:57
	System	12 Jan 2021 02:12:57

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-11T20:12:46', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '266d83cc-a7b0-4e15-98a4-f7eb899598d8' User entered 'No (N)'	System	12 Jan 2021 02:12:57
	System	12 Jan 2021 02:12:57

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-11T20:12:52', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '266d83cc-a7b0-4e15-98a4-f7eb899598d8' User entered '11 Jan 2021 20:12:52'	System	12 Jan 2021 02:12:57
	System	12 Jan 2021 02:12:57

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-18T21:54:56', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '9c3056f0-4b5c-4cc5-82a1-2754123169bb'	System	19 Jan 2021 03:55:44
User entered 'No (N)'	System	19 Jan 2021 03:55:44

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-18T21:55:14', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '9c3056f0-4b5c-4cc5-82a1-2754123169bb' User entered 'No (N)'	System	19 Jan 2021 03:55:44
	System	19 Jan 2021 03:55:44

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-18T21:55:41', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '9c3056f0-4b5c-4cc5-82a1-2754123169bb' User entered '18 Jan 2021 21:55:41'	System	19 Jan 2021 03:55:44
	System	19 Jan 2021 03:55:44

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-25T21:04:02', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '660d314e-1452-49b6-a911-07007450ac09'	System	26 Jan 2021 03:04:17
User entered 'No (N)'	System	26 Jan 2021 03:04:17

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-25T21:04:08', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '660d314e-1452-49b6-a911-07007450ac09'	System	26 Jan 2021 03:04:17
User entered 'No (N)'	System	26 Jan 2021 03:04:17

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-01-25T21:04:15', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '660d314e-1452-49b6-a911-07007450ac09'	System	26 Jan 2021 03:04:17
User entered '25 Jan 2021 21:04:15'	System	26 Jan 2021 03:04:17

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-02-08T22:37:23', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '60fb32d3-1a7e-49ac-a310-d1029685bf16'	System	09 Feb 2021 04:37:38
User entered 'No (N)'	System	09 Feb 2021 04:37:38

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-02-08T22:37:28', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '60fb32d3-1a7e-49ac-a310-d1029685bf16'	System	09 Feb 2021 04:37:38
User entered 'No (N)'	System	09 Feb 2021 04:37:38

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-02-08T22:37:36', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '60fb32d3-1a7e-49ac-a310-d1029685bf16'	System	09 Feb 2021 04:37:38
User entered '08 Feb 2021 22:37:36'	System	09 Feb 2021 04:37:38

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-02-15T19:38:20', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '13a96698-b920-40fb-89a3-cfcb92b3091c' User entered 'No (N)'	System	16 Feb 2021 01:38:39
	System	16 Feb 2021 01:38:39

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-02-15T19:38:30', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '13a96698-b920-40fb-89a3-cfcb92b3091c' User entered 'No (N)'	System	16 Feb 2021 01:38:39
	System	16 Feb 2021 01:38:39

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-02-15T19:38:35', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '13a96698-b920-40fb-89a3-cfcb92b3091c' User entered '15 Feb 2021 19:38:35'	System	16 Feb 2021 01:38:39
	System	16 Feb 2021 01:38:39

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-01T18:55:28', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '40ea9344-b8b5-42ec-8169-afeb6b37f3f7'	System	02 Mar 2021 00:55:44
User entered 'No (N)'	System	02 Mar 2021 00:55:44

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-01T18:55:33', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '40ea9344-b8b5-42ec-8169-afeb6b37f3f7'	System	02 Mar 2021 00:55:44
User entered 'No (N)'	System	02 Mar 2021 00:55:44

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-01T18:55:40', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '40ea9344-b8b5-42ec-8169-afeb6b37f3f7'	System	02 Mar 2021 00:55:44
User entered '01 Mar 2021 18:55:40'	System	02 Mar 2021 00:55:44

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-08T12:51:47', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '4d7c676c-29af-48d8-b3b5-eb0e190606c5' User entered 'No (N)'	System	08 Mar 2021 18:52:13
	System	08 Mar 2021 18:52:13

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-08T12:51:55', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '4d7c676c-29af-48d8-b3b5-eb0e190606c5'	System	08 Mar 2021 18:52:13
User entered 'No (N)'	System	08 Mar 2021 18:52:13

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-08T12:52:10', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '4d7c676c-29af-48d8-b3b5-eb0e190606c5' User entered '08 Mar 2021 12:52:10'	System	08 Mar 2021 18:52:13
	System	08 Mar 2021 18:52:13

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-15T18:38:35', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '52672c73-8149-4314-bff0-f9b6fa068479'	System	15 Mar 2021 23:38:52
User entered 'No (N)'	System	15 Mar 2021 23:38:52

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-15T18:38:42', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '52672c73-8149-4314-bff0-f9b6fa068479'	System	15 Mar 2021 23:38:52
User entered 'No (N)'	System	15 Mar 2021 23:38:52

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-15T18:38:50', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '52672c73-8149-4314-bff0-f9b6fa068479' User entered '15 Mar 2021 18:38:50'	System	15 Mar 2021 23:38:52
	System	15 Mar 2021 23:38:52

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-22T18:31:34', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '78c6d102-c125-436e-974c-8f61dd4d4e96'	System	22 Mar 2021 23:31:50
User entered 'No (N)'	System	22 Mar 2021 23:31:50

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-22T18:31:41', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '78c6d102-c125-436e-974c-8f61dd4d4e96'	System	22 Mar 2021 23:31:50
User entered 'No (N)'	System	22 Mar 2021 23:31:50

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-22T18:31:48', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '78c6d102-c125-436e-974c-8f61dd4d4e96' User entered '22 Mar 2021 18:31:48'	System	22 Mar 2021 23:31:50
	System	22 Mar 2021 23:31:50

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-29T20:22:33', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a31ad93c-aadf-4ddc-b3e7-e1e205eb1270'	System	30 Mar 2021 01:28:17
User entered 'No (N)'	System	30 Mar 2021 01:28:17

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-29T20:22:41', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a31ad93c-aadf-4ddc-b3e7-e1e205eb1270'	System	30 Mar 2021 01:28:17
User entered 'No (N)'	System	30 Mar 2021 01:28:17

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-29T20:22:49', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a31ad93c-aadf-4ddc-b3e7-e1e205eb1270' User entered '29 Mar 2021 20:22:49'	System	30 Mar 2021 01:28:17
	System	30 Mar 2021 01:28:17

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-04-05T12:10:17', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '221416f6-3751-49ee-9b52-096ce88651f1' User entered 'No (N)'	System	05 Apr 2021 17:11:41
	System	05 Apr 2021 17:11:41

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-04-05T12:10:33', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '221416f6-3751-49ee-9b52-096ce88651f1'	System	05 Apr 2021 17:11:41
User entered 'No (N)'	System	05 Apr 2021 17:11:41

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-04-05T12:10:37', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '221416f6-3751-49ee-9b52-096ce88651f1' User entered '05 Apr 2021 12:10:37'	System	05 Apr 2021 17:11:41
	System	05 Apr 2021 17:11:41

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-04-12T17:59:56', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '267d1487-a2cb-4d26-9514-9e4ace4ce959' User entered 'No (N)'	System	19 Apr 2021 21:07:15
	System	19 Apr 2021 21:07:15

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-04-12T18:00:02', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '267d1487-a2cb-4d26-9514-9e4ace4ce959' User entered 'No (N)'	System	19 Apr 2021 21:07:15
	System	19 Apr 2021 21:07:15

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-04-12T18:00:06', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '267d1487-a2cb-4d26-9514-9e4ace4ce959'	System	19 Apr 2021 21:07:15
User entered '12 Apr 2021 18:00:06'	System	19 Apr 2021 21:07:15

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-04-19T16:07:28', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'fc481865-bedd-4e26-ae6d-f161ddcb25ed' User entered 'No (N)'	System	19 Apr 2021 21:07:41

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-04-19T16:07:35', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'fc481865-bedd-4e26-ae6d-f161ddcb25ed' User entered 'No (N)'	System	19 Apr 2021 21:07:41

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-04-19T16:07:38', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'fc481865-bedd-4e26-ae6d-f161ddcb25ed' User entered '19 Apr 2021 16:07:38'	System	19 Apr 2021 21:07:41
	System	19 Apr 2021 21:07:41

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-04-26T20:33:52', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a30b6085-75af-415b-bef3-f2665811874f' User entered 'No (N)'	System	27 Apr 2021 01:34:18
	System	27 Apr 2021 01:34:18

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-04-26T20:34:05', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a30b6085-75af-415b-bef3-f2665811874f'	System	27 Apr 2021 01:34:18
User entered 'No (N)'	System	27 Apr 2021 01:34:18

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-04-26T20:34:13', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'a30b6085-75af-415b-bef3-f2665811874f'	System	27 Apr 2021 01:34:18
User entered '26 Apr 2021 20:34:13'	System	27 Apr 2021 01:34:18

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-05-03T17:57:58', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '486be04f-0a6a-45c2-83ad-03866d1d6c42'	System	03 May 2021 22:58:12
User entered 'No (N)'	System	03 May 2021 22:58:12

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Have you been exposed to someone with 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 (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-05-03T17:58:01', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '486be04f-0a6a-45c2-83ad-03866d1d6c42'	System	03 May 2021 22:58:12
User entered 'No (N)'	System	03 May 2021 22:58:12

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-05-03T17:58:07', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: '486be04f-0a6a-45c2-83ad-03866d1d6c42'	System	03 May 2021 22:58:12
User entered '03 May 2021 17:58:07'	System	03 May 2021 22:58:12

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 06:04:23

US3912121

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:17:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:04:23
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 06:04:23

US3912121

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:17:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:30:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-01T18:55:55', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'fed2554-87bd-44bf-9dff-6dd60a311d55'	System	02 Mar 2021 00:56:10
User entered 'No (N)'	System	02 Mar 2021 00:56:10

US3912121

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:17:58

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:30:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A3E784CF-36F4-4CB0-86A8-452833A5C970)', Time: '2021-03-01T18:56:08', User OID: 'PatientReportedOutcome (US3912121)', ODM File OID: 'fed2554-87bd-44bf-9dff-6dd60a311d55'	System	02 Mar 2021 00:56:10
User entered '01 Mar 2021 18:56:08'	System	02 Mar 2021 00:56:10

US3912121

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	01 Dec 2020 19:12:33

US3912121

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '1 Dec 2020'	Sandra Clancy (b) (4)	01 Dec 2020 19:12:33

US3912121

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Contact Made (CONTACT MADE)'	Sandra Clancy (b) (4)	01 Dec 2020 19:12:33

US3912121

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Sandra Clancy (b) (4)	01 Dec 2020 19:12:33

US3912121

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	01 Dec 2020 19:12:37

US3912121

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 07:23:40
User entered 'I'	System	01 Dec 2020 19:12:37

US3912121

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	11 Jan 2021 20:18:45

US3912121

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '5 Jan 2021'	Sandra Clancy (b) (4)	11 Jan 2021 20:18:45

US3912121

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Contact Made (CONTACT MADE)'	Sandra Clancy (b) (4)	11 Jan 2021 20:18:45

US3912121

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	Sandra Clancy (b) (4)	11 Jan 2021 20:18:45

US3912121

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	11 Jan 2021 20:18:50

US3912121

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User entered 'I'	System	11 Jan 2021 20:18:50

US3912121

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:13:01

US3912121

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 09:13:33
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'confirmed that day 149 safety call completed greater than 123 days after visit 2' (Site from System).	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:13:30
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	09 Feb 2021 17:13:01
User entered '8 Feb 2021'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:13:01

US3912121

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:13:01

US3912121

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:13:01

US3912121

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	09 Feb 2021 17:13:41

US3912121

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User entered 'I'	System	09 Feb 2021 17:13:41

US3912121

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	02 Mar 2021 18:34:57

US3912121

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '2 Mar 2021'	Sandra Clancy (b) (4)	02 Mar 2021 18:34:57

US3912121

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	02 Mar 2021 18:34:57

US3912121

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	Sandra Clancy (b) (4)	02 Mar 2021 18:34:57

US3912121

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	02 Mar 2021 18:35:02

US3912121

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User entered 'I'	System	02 Mar 2021 18:35:02

US3912121

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	30 Mar 2021 16:00:38

US3912121

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered '30 Mar 2021'	(b) (4) Sandra Clancy (b) (4)	30 Mar 2021 16:00:38

US3912121

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered 'Clinic (Clinic)'	Sandra Clancy (b) (4)	30 Mar 2021 16:00:38

US3912121

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User entered 'VISIT4'	System	30 Mar 2021 16:00:38

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered '30 Mar 2021'	Sandra Clancy (b) (4)	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered '09:28'	Sandra Clancy (b) (4)	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User entered '30 Mar 2021 09:28'	System	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered '97.8' F	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered 'Oral (Oral)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered '56'	Sandra Clancy (b) (4)	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User entered 'bpm'	System	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered '12'	Sandra Clancy (b) (4)	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User entered 'breaths/min'	System	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered '172'	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User entered 'mmHg'	System	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered '81'	Sandra Clancy (b) (4)	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User entered 'mmHg'	System	30 Mar 2021 16:01:22

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36

US3912121

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36

US3912121

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered 'No (N)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	30 Mar 2021 16:01:27

US3912121

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered empty.	Sandra Clancy (b) (4)	30 Mar 2021 16:01:27

US3912121

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	30 Mar 2021 16:01:51

US3912121

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered '30 Mar 2021'	Sandra Clancy (b) (4)	30 Mar 2021 16:01:51

US3912121

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered '09:59'	Sandra Clancy (b) (4)	30 Mar 2021 16:01:51

US3912121

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User entered '30 Mar 2021 09:59'	System	30 Mar 2021 16:01:51

US3912121

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	30 Mar 2021 16:01:56

US3912121

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:09:36
User entered 'I'	System	30 Mar 2021 16:01:56

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Mia Rountree (b) (4)	15 Jan 2021 22:09:00

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '12 Jan 2021'	Mia Rountree (b) (4)	15 Jan 2021 22:09:00

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[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 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Clinic (Clinic)'	Mia Rountree (b) (4)	15 Jan 2021 22:09:00

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 22:09:00

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:17:58

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '12 Jan 2021'	Mia Rountree (b) (4)	15 Jan 2021 22:10:09

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:17:58

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	12 Mar 2021 19:11:42
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:49:14

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:17:58

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Mia Rountree (b) (4)	15 Jan 2021 22:10:09

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:17:58

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	12 Mar 2021 19:11:42
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:49:14

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:17:58

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '12 Jan 2021'	Mia Rountree (b) (4)	15 Jan 2021 22:10:09

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:17:58

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Placebo (Placebo)'	Mia Rountree (b) (4)	15 Jan 2021 22:10:09

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:17:58

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 14:22:31
User entered 'Placebo (Placebo)'	Mia Rountree (b) (4)	15 Jan 2021 22:10:09
	(b) (4)	

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:17:58

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 14:22:31
User entered 'Placebo (Placebo)'	Mia Rountree (b) (4)	15 Jan 2021 22:10:09
	(b) (4)	

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:17:58

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)' reason for change: New Information	Tina Rountree (b) (4)	09 Feb 2021 20:52:48
User entered 'No (N)'	Mia Rountree (b) (4)	15 Jan 2021 22:10:09

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:17:58

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered '1'	System	15 Jan 2021 22:10:09

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:17:58

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'I'	System	09 Feb 2021 20:52:48
User entered empty.	System	15 Jan 2021 22:10:09

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered empty.	System	09 Feb 2021 20:54:55
DataPoint set to visible.	System	09 Feb 2021 20:52:48

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered empty.	System	09 Feb 2021 20:54:55
DataPoint set to visible.	System	09 Feb 2021 20:52:48

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User accepted default value 'Pre-Dose (PREDOSE)'	Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:45:23
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:54:55
User entered '8 Feb 2021'	Tina Rountree (b) (4) (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '12:40'	Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered '8 Feb 2021 12:40'	System	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '98.5' F	Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Oral (Oral)'	Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '71'	Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'bpm'	System	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '12'	Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'breaths/min'	System	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '139'	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'mmHg'	System	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '82'	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'mmHg'	System	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:17:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered empty.	System	09 Feb 2021 20:54:55
DataPoint set to visible.	System	09 Feb 2021 20:52:48

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User accepted default value 'Post-Dose (POSTDOSE)'	Tina Rountree (b) (4) (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:45:31
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:54:55
User entered '8 Feb 2021'	Tina Rountree (b) (4) (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '14:35'	Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered '8 Feb 2021 14:35'	System	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '36.6' C	Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Oral (Oral)'	Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '88'	Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'bpm'	System	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '18'	Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'breaths/min'	System	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '134'	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'mmHg'	System	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '65'	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'mmHg'	System	09 Feb 2021 20:54:55

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:55:20

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:44:08
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:55:20
User entered '8 Feb 2021'	Tina Rountree (b) (4) (b) (4)	09 Feb 2021 20:55:20

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:55:57

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:55:57

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	Tina Rountree (b) (4)	09 Feb 2021 20:55:57

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'mRNA-1273'	System	09 Feb 2021 20:55:57
DataPoint set to visible.	System	09 Feb 2021 20:52:48

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:43:57
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:55:57
User entered '8 Feb 2021'	Tina Rountree (b) (4) (b) (4)	09 Feb 2021 20:55:57

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '13:52'	Tina Rountree (b) (4)	09 Feb 2021 20:55:57

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered '8 Feb 2021 13:52'	System	09 Feb 2021 20:55:57

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tina Rountree (b) (4)	09 Feb 2021 20:55:57

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'ONCE'	System	09 Feb 2021 20:55:57

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 20:55:57

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Mia Rountree (b) (4)	15 Jan 2021 22:10:34

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '12 Jan 2021'	Mia Rountree (b) (4)	15 Jan 2021 22:10:34

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '13:47'	Mia Rountree (b) (4)	15 Jan 2021 22:10:34

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered '12 Jan 2021 13:47'	System	15 Jan 2021 22:10:34

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:17:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Mia Rountree (b) (4)	15 Jan 2021 22:10:54

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:17:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '12 Jan 2021'	Mia Rountree (b) (4)	15 Jan 2021 22:10:54

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:17:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered '13:51'	Mia Rountree (b) (4)	15 Jan 2021 22:10:54

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:17:58

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered '12 Jan 2021 13:51'	System	15 Jan 2021 22:10:54

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
User entered 'Yes (Y)'	Tina Rountree (b) (4)	09 Feb 2021 20:56:03

US3912121

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'I'	System	09 Feb 2021 20:56:03

US3912121

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 18:56:16

US3912121

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 13:09:01
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'due to inclement weather safety call was completed out of window' (Site from System).	(b) (4), (b) (6)	21 Feb 2021 19:46:08
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Feb 2021 18:56:16
User entered '20 Feb 2021'	(b) (4), (b) (6)	21 Feb 2021 18:56:16

US3912121

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 18:56:16

US3912121

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Feb 2021 18:56:16

US3912121

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Feb 2021 18:56:26

US3912121

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'I'	System	21 Feb 2021 18:56:26

US3912121

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'I'	System	21 Feb 2021 18:56:26
DataPoint set to visible.	System	21 Feb 2021 18:56:26

US3912121

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 14:37:17

US3912121

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '5 Mar 2021'	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 14:37:17

US3912121

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[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 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Clinic (Clinic)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 14:37:17

US3912121

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'OLD29'	System	08 Mar 2021 14:37:17

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User accepted default value 'Pre-Dose (PREDOSE)'	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '5 Mar 2021'	Sandra Clancy (b) (4)	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '13:32'	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered '5 Mar 2021 13:32'	System	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '97.9' F	Sandra Clancy (b) (4)	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Oral (Oral)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '55'	(b) (4) Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'bpm'	System	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '16'	Sandra Clancy (b) (4)	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'breaths/min'	System	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '130'	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'mmHg'	System	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '81'	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'mmHg'	System	08 Mar 2021 14:38:02

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User accepted default value 'Post-Dose (POSTDOSE)'	Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '5 Mar 2021'	Sandra Clancy (b) (4)	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '15:42'	Sandra Clancy (b) (4)	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered '5 Mar 2021 15:42'	System	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '98.2' F	Sandra Clancy (b) (4)	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Oral (Oral)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '65'	(b) (4) Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'bpm'	System	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '16'	Sandra Clancy (b) (4)	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'breaths/min'	System	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '165'	(b) (4) Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'mmHg'	System	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '84'	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'mmHg'	System	08 Mar 2021 14:38:59

US3912121

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 14:39:16

US3912121

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '5 Mar 2021'	Sandra Clancy (b) (4)	08 Mar 2021 14:39:16

US3912121

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 14:39:34

US3912121

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 14:39:34

US3912121

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	Sandra Clancy (b) (4)	08 Mar 2021 14:39:34

US3912121

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'mRNA-1273'	System	08 Mar 2021 14:39:34
DataPoint set to visible.	System	21 Feb 2021 18:56:26

US3912121

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '5 Mar 2021'	(b) (4) Sandra Clancy (b) (4)	08 Mar 2021 14:39:34

US3912121

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '14:57'	Sandra Clancy (b) (4)	08 Mar 2021 14:39:34

US3912121

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered '5 Mar 2021 14:57'	System	08 Mar 2021 14:39:34

US3912121

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Left Arm (LEFT ARM)'	Sandra Clancy (b) (4)	08 Mar 2021 14:39:34

US3912121

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'ONCE'	System	08 Mar 2021 14:39:34

US3912121

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:17:58

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'INTRAMUSCULAR'	System	08 Mar 2021 14:39:34

US3912121

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Yes (Y)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	08 Mar 2021 14:39:40

US3912121

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'I'	System	08 Mar 2021 14:39:40

US3912121

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	16 Mar 2021 21:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 22:11:44

US3912121

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	16 Mar 2021 21:17:02
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 22:11:44

US3912121

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	16 Mar 2021 21:17:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 22:11:44

US3912121

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:17:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	16 Mar 2021 21:17:02
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 22:11:44

US3912121

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User signature succeeded.	Mark Hutchens (b) (4)	16 Mar 2021 21:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 22:11:55

US3912121

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:17:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:53:28
User entered 'I'	System	15 Mar 2021 22:11:55

US3912121

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	30 Mar 2021 16:02:09
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered '30 Mar 2021'	Sandra Clancy (b) (4)	30 Mar 2021 16:02:09
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered 'Clinic (Clinic)'	Sandra Clancy (b) (4)	30 Mar 2021 16:02:09
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:17:58

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 16:02:09

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	30 Mar 2021 16:02:45
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered '30 Mar 2021'	Sandra Clancy (b) (4)	30 Mar 2021 16:02:45
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered '09:28'	Sandra Clancy (b) (4)	30 Mar 2021 16:02:45
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 09:28'	System	30 Mar 2021 16:02:45

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered '97.8' F	Sandra Clancy (b) (4)	30 Mar 2021 16:02:45
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered 'Oral (Oral)'	Sandra Clancy (b) (4)	30 Mar 2021 16:02:45
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	30 Mar 2021 16:02:45
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered '56'	Sandra Clancy (b) (4)	30 Mar 2021 16:02:45
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 16:02:45

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered '12'	Sandra Clancy (b) (4)	30 Mar 2021 16:02:45
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 16:02:45

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered '172'	Sandra Clancy (b) (4)	30 Mar 2021 16:02:45
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 16:02:45

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered '81'	Sandra Clancy (b) (4)	30 Mar 2021 16:02:45
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:17:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 16:02:45

US3912121

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered 'No (N)'	Sandra Clancy (b) (4)	30 Mar 2021 16:02:50
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:17:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	30 Mar 2021 16:02:50
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	30 Mar 2021 16:03:10
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered '30 Mar 2021'	Sandra Clancy (b) (4)	30 Mar 2021 16:03:10
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	31 Mar 2021 17:52:14
	(b) (4)	
User entered '09:59'	Sandra Clancy (b) (4)	30 Mar 2021 16:03:10
	(b) (4)	

US3912121

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:17:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 09:59'	System	30 Mar 2021 16:03:10

US3912121

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:17:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:56
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 117, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 06:03:21
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 117, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'completed with SAE ' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	01 Apr 2021 00:20:01
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 117, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 03:52:26
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:51:52
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:35:34

US3912121

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:58

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 18:48:44
Reviewed for Safety.	(b) (4), (b) (6)	23 Dec 2020 15:37:03
User entered	(b) (4), (b) (6)	23 Dec 2020 15:36:59
'USA-US211-2020-mRNA-1273-P301000009'		

US3912121

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 18:48:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 17:08:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	28 Dec 2020 17:08:22
Data point term sent to Coder	System	28 Dec 2020 17:08:10
DataPoint Un-verified.	Sandra Clancy (b) (4)	28 Dec 2020 17:07:56
	(b) (4)	
Coding entries removed.	Sandra Clancy (b) (4)	28 Dec 2020 17:07:56
	(b) (4)	
User entered 'small bowel obstruction' reason for change: New Information	Sandra Clancy (b) (4)	28 Dec 2020 17:07:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4)	19 Dec 2020 21:41:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Dec 2020 21:41:41
Data point term sent to Coder	System	19 Dec 2020 21:40:30
User entered 'Abdominal Pain'	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

US3912121

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:40:14

US3912121

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:40:14

US3912121

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:40:14

US3912121

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered '17 Dec 2020'	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

US3912121

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered empty.	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:40:14

US3912121

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Dec 2020 21:40:14

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:48:48
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Dec 2020 21:40:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Dec 2020 21:40:57
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:40:57
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Dec 2020 21:40:14
User entered empty.	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:40:14

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered '18 Dec 2020'	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:58

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered empty.	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Dec 2020 21:40:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:48:01
User entered 'Grade 4 (Grade 4)'	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:48:22
User closed query 'Per CDM: Re query: Response noted. Please check for AE (Abdominal pain) severity is mentioned as Grade 4, however 'Is the adverse event serious?' is marked as No. Kindly reconcile the data and update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 15:49:45
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	22 Dec 2020 23:38:02
Query 'Per CDM: Re query: Response noted. Please check for AE (Abdominal pain) severity is mentioned as Grade 4, however 'Is the adverse event serious?' is marked as No. Kindly reconcile the data and update accordingly.' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 23:37:31
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	22 Dec 2020 23:37:18
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 23:37:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 23:37:18
User opened query 'Per CDM: Re query: Response noted. Please check for AE (Abdominal pain) severity is mentioned as Grade 4, however 'Is the adverse event serious?' is marked as No. Kindly reconcile the data and update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 15:28:17
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4), (b) (6)	22 Dec 2020 15:24:50
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:47:58

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Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'abdominal pain lead to an AE that was serious and will be entered. ' (Site from System). User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System). User entered 'No (N)'	Tina Rountree (b) (4)	19 Dec 2020 21:40:53
		19 Dec 2020 21:40:14
	Tina Rountree (b) (4)	19 Dec 2020 21:40:14

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered '0'	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered '0'	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:48:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	28 Dec 2020 15:50:24
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 'added details' (Site from System).	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 23:51:42
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	22 Dec 2020 23:38:02
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 23:38:02
User entered '1' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 23:38:02
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered '0'	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:40:14

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Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:48:27
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 23:51:23
User entered '18 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	22 Dec 2020 23:51:23
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered empty.	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:40:14

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Form: Adverse Events (2)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Query 'PV Query: Please clarify why the subject remained hospitalized until 28 Dec 2020, but the event paroxysmal atrial fibrillation ended on 25 Dec 2020. Please update accordingly.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 15:11:09
User opened query 'PV Query: Please clarify why the subject remained hospitalized until 28 Dec 2020, but the event paroxysmal atrial fibrillation ended on 25 Dec 2020. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:10:13
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:48:29
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:25:10
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	04 Jan 2021 21:50:03
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	04 Jan 2021 21:49:53
User entered '28 Dec 2020' reason for change: New Information	Sandra Clancy (b) (4) (b) (4)	04 Jan 2021 21:49:53
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 20:12:23
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered empty.	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:40:14

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 18:48:30
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	04 Jan 2021 22:20:56
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		04 Jan 2021 22:20:56
User entered 'No (N)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	04 Jan 2021 22:20:56
	(b) (4)	
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	04 Jan 2021 21:49:53
DataPoint Un-verified.	Sandra Clancy (b) (4)	04 Jan 2021 21:49:53
	(b) (4)	
User entered 'Unknown (UNK)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	04 Jan 2021 21:49:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered empty.	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered empty.	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered '0'	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered '0'	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered '0'	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:40:14

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered 'Not Related (NOT RELATED)'	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:40:14

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Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered 'Not Applicable (NOT APPLICABLE)'	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:40:14

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered '0'	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:37:33
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there were ConMed #8 and 9 recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:43:40
Query 'Per DM CLR: Please review and verify if this field should be ticked as there were ConMed #8 and 9 recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 23:48:31
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 23:48:20
User entered '1' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 23:48:20
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there were ConMed #8 and 9 recorded that mach this AE during this timeframe. Review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:34:46
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered '0'	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:40:14

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered 'I'	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:11:34
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	26 Jan 2021 00:36:26
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	26 Jan 2021 00:34:40
DataPoint Un-verified.	Sandra Clancy (b) (4)	26 Jan 2021 00:34:40
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	26 Jan 2021 00:34:40
	(b) (4)	
Query 'PV Query: The event, small bowel obstruction, was reported as resolved with sequelae. Please provide the sequelae.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:10:34
User opened query 'PV Query: The event, small bowel obstruction, was reported as resolved with sequelae. Please provide the sequelae.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:10:28
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:48:33
DataPoint Un-verified.	Sandra Clancy (b) (4)	22 Dec 2020 23:51:23
	(b) (4)	
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	22 Dec 2020 23:51:23
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:11:36
DataPoint Un-verified.	Sandra Clancy (b) (4)	26 Jan 2021 00:36:26
	(b) (4)	
User entered empty; reason for change Data Entry Error	Sandra Clancy (b) (4)	26 Jan 2021 00:36:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 18:48:36
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	23 Dec 2020 00:00:41
DataPoint Un-verified.	Sandra Clancy (b) (4)	23 Dec 2020 00:00:41
	(b) (4)	
User entered 'She underwent a transthoracic echocardiogram to follow up on episode of atrial fibrillation; conclusions- mild-moderate regurgitation of the mitral and tricuspid valve.Left atrium was severely dilate' reason for change: Data Entry Error	Sandra Clancy (b) (4)	23 Dec 2020 00:00:41
	(b) (4)	
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	22 Dec 2020 23:51:23
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered empty.	Tina Rountree (b) (4)	19 Dec 2020 21:40:14
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User closed query 'Per DM CLR: Narrative = CT OF ABDOMEN AND PELVIS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:45:56
Query 'Per DM CLR: Narrative = CT OF ABDOMEN AND PELVIS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:03:59
User opened query 'Per DM CLR: Narrative = CT OF ABDOMEN AND PELVIS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:34:40
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 18:48:38
User entered 'THE SUBJECT INITIALLY PRESENTED TO THE ER WITH ABDOMINAL PAIN STARTING THE DAY PRIOR; THE PAIN IS DESCRIBED AS SHARP, ACHY LOWER ABDOMINAL PAIN WITHOUT RADIATION WITH ASSOCIATED INTRACTABLE NAUSEA AND VOMITING. UPON EXAMINATION THERE WAS ABDOMINAL DISTENTION NOTED WITH TENDERNESS AND SILENT BOWEL SOUNDS. SHE WAS IMMEDIATELY SENT FOR CT OF ABDOMEN AND PELVIS WHICH REVEALED CLOSED LOOP SMALL BOWEL OBSTRUCTION FOR WHICH SHE WAS SCHEDULED FOR EMERGENT SURGERY. THE INITIAL RECOMMENDATION FROM CONSULTATION WAS TO UNDERGO URGENT DIAGNOSTIC LAPAROSCOPY WITH POSSIBLE LAPAROTOMY; HOWEVER IN THE OR THE EXPLORATORY LAPAROSCOPY CONVERTED TO OPEN BOWEL RESECTION. note: subject had negative Covid test on admission 18Dec2020.' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	23 Dec 2020 00:04:51

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Dec 2020 23:49:53
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Dec 2020 23:49:53
DataPoint Un-verified.	Sandra Clancy (b) (4)	22 Dec 2020 23:49:53
User entered 'The subject initially presented to the ER with abdominal pain starting the day prior; the pain is described as sharp, achy lower abdominal pain without radiation with associated intractable nausea and vomiting. Upon examination there was abdominal distention noted with tenderness and silent bowel sounds. She was immediately sent for CT of abdomen and pelvis which revealed closed loop small bowel obstruction for which she was scheduled for emergent surgery. The initial recommendation from consultation was to undergo urgent diagnostic laparoscopy with possible laparotomy; however in the OR the exploratory laparoscopy converted to open bowel resection.' reason for change: Data Entry Error	Sandra Clancy (b) (4)	22 Dec 2020 23:49:53
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Dec 2020 23:37:18
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:48:48
User entered empty.	Tina Rountree (b) (4)	19 Dec 2020 21:40:14

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Dec 2020 23:37:18
User entered '0'	System	19 Dec 2020 21:40:14

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Dec 2020 21:40:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:17:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Jan 2021 21:49:53

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	08 Jan 2021 23:15:32
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 14:14:24
User entered	(b) (4), (b) (6)	29 Dec 2020 14:14:20
'USA-US211-2020-mRNA-1273-P301000009'		

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of ATRIAL FIBRILLATION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:47:51
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of ATRIAL FIBRILLATION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'subject had episode of PAF - not worsening' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:05:44
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of ATRIAL FIBRILLATION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:35:34
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Dec 2020 18:52:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Dec 2020 18:52:25
Data point term sent to Coder	System	28 Dec 2020 18:51:39
User entered 'Paroxysmal atrial fibrillation'	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered '20 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	04 Jan 2021 21:52:51
User entered '21 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 18:51:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered 'No (N)' reason for change: New Information	Sandra Clancy (b) (4) (b) (4)	04 Jan 2021 21:52:51
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User closed query 'PV Query: Please clarify why the subject remained hospitalized until 28 Dec 2020, but the event paroxysmal atrial fibrillation ended on 25 Dec 2020. Please update accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:45:12
Query 'PV Query: Please clarify why the subject remained hospitalized until 28 Dec 2020, but the event paroxysmal atrial fibrillation ended on 25 Dec 2020. Please update accordingly.' answered with 'the hospitalization was NOT for paroxysmal a-fib - the event of a-fib occurred while the subject was recovering from surgery.' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:07:39
User opened query 'PV Query: Please clarify why the subject remained hospitalized until 28 Dec 2020, but the event paroxysmal atrial fibrillation ended on 25 Dec 2020. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 23:59:10
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:25:50
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).	Sandra Clancy (b) (4) (b) (4)	04 Jan 2021 21:53:08
User entered '25 Dec 2020' reason for change: New Information	Sandra Clancy (b) (4) (b) (4)	04 Jan 2021 21:52:51
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 Dec 2020 20:14:07
User entered empty.	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	04 Jan 2021 21:53:40
User entered empty; reason for change New Information	Sandra Clancy (b) (4)	04 Jan 2021 21:53:40
	(b) (4)	
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	04 Jan 2021 21:52:51
User entered '14:00' reason for change: New Information	Sandra Clancy (b) (4)	04 Jan 2021 21:52:51
	(b) (4)	
User entered empty.	Sandra Clancy (b) (4)	28 Dec 2020 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 21:53:40
User entered '25 Dec 2020 14:00'	System	04 Jan 2021 21:52:51
User entered empty.	System	28 Dec 2020 18:51:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:12:19
User closed query 'PV Query: Since the subject was hospitalized during the event of paroxysmal atrial fibrillation, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 15:39:21
Query 'PV Query: Since the subject was hospitalized during the event of paroxysmal atrial fibrillation, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' answered with 'corrected per your query' (Site from Safety).	Sandra Clancy (b) (4)	26 Jan 2021 00:32:58
DataPoint Un-verified.	(b) (4)	
	Sandra Clancy (b) (4)	22 Jan 2021 00:48:21
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4)	
	Sandra Clancy (b) (4)	22 Jan 2021 00:48:21
User opened query 'PV Query: Since the subject was hospitalized during the event of paroxysmal atrial fibrillation, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:13:27
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Jan 2021 21:52:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Jan 2021 21:52:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Sandra Clancy (b) (4)	04 Jan 2021 21:52:51
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 18:51:01
User entered empty.	Sandra Clancy (b) (4)	28 Dec 2020 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered 'Yes (Y)'	Sandra Clancy (b) (4)	28 Dec 2020 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered '0'	Sandra Clancy (b) (4)	28 Dec 2020 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered '0'	Sandra Clancy (b) (4)	28 Dec 2020 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:32
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)	29 Dec 2020 12:42:43
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'corrected' (Site from System).	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:56:16
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	28 Dec 2020 18:51:01
User entered 'I'	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered '18 Dec 2020' reason for change: Data Entry Error	Sandra Clancy (b) (4)	28 Dec 2020 18:55:46
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User closed query 'PV Query: Please clarify why the subject remained hospitalized until 28 Dec 2020, but the event paroxysmal atrial fibrillation ended on 25 Dec 2020. Please update accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:06:45
Query 'PV Query: Please clarify why the subject remained hospitalized until 28 Dec 2020, but the event paroxysmal atrial fibrillation ended on 25 Dec 2020. Please update accordingly.' answered with 'The subject remained in the hospital after resolution of PAF due to emergent surgery to correct small bowel obstruction. Subject has a medical history of PAF and it has been under control until the episode following this surgery.' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	22 Jan 2021 00:51:00
User opened query 'PV Query: Please clarify why the subject remained hospitalized until 28 Dec 2020, but the event paroxysmal atrial fibrillation ended on 25 Dec 2020. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:12:16
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered '28 Dec 2020' reason for change: New Information	Sandra Clancy (b) (4) (b) (4)	04 Jan 2021 21:52:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered 'Yes (Y)' reason for change: New Information	Sandra Clancy (b) (4) (b) (4)	04 Jan 2021 22:20:27
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered '10' reason for change: New Information	Sandra Clancy (b) (4) (b) (4)	04 Jan 2021 22:20:27
User entered empty.	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered '0'	Sandra Clancy (b) (4)	28 Dec 2020 18:51:01
	(b) (4)	

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered '0'	Sandra Clancy (b) (4)	28 Dec 2020 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered '0'	Sandra Clancy (b) (4)	28 Dec 2020 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:25:46
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	Sandra Clancy (b) (4)	04 Jan 2021 21:54:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Jan 2021 21:52:51
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	04 Jan 2021 21:52:51
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	Sandra Clancy (b) (4)	04 Jan 2021 21:52:51
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:12:01
	System	28 Dec 2020 18:51:01
	Sandra Clancy (b) (4)	28 Dec 2020 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:25:44
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	Sandra Clancy (b) (4)	04 Jan 2021 21:54:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Jan 2021 21:52:51
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	04 Jan 2021 21:52:51
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	Sandra Clancy (b) (4)	04 Jan 2021 21:52:51
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:12:11
	System	28 Dec 2020 18:51:01
	Sandra Clancy (b) (4)	28 Dec 2020 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered 'Not Applicable (NOT APPLICABLE)'	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered '0'	Sandra Clancy (b) (4)	28 Dec 2020 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User closed query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Jan 2021 17:00:57
Query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' answered with 'there are SIX 6 entries in the con meds to speak to this event.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	22 Jan 2021 00:53:29
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User opened query 'Per CDM : Please note that Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 18:33:38
User entered 'I'	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered '0'	Sandra Clancy (b) (4)	28 Dec 2020 18:51:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:32
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:25:41
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'event resolved' (Site from Safety).	Sandra Clancy (b) (4) (b) (4)	04 Jan 2021 21:54:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Sandra Clancy (b) (4) (b) (4)	04 Jan 2021 21:52:51
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 20:14:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered empty.	Sandra Clancy (b) (4) (b) (4)	28 Dec 2020 18:51:01

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User closed query 'Per DM CLR: Narrative = DILATED IVC. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:50:59
User closed query 'Per DM CLR: Narrative = MULTIPLE CARDIOVERSIONS AND ABLATION IN 2012. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 17:50:39
Query 'Per DM CLR: Narrative = DILATED IVC. 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 'not a separate event - all related to the episode of paroxysmal a-fib' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:45:29
Query 'Per DM CLR: Narrative = MULTIPLE CARDIOVERSIONS AND ABLATION IN 2012. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:24:26
User opened query 'Per DM CLR: Narrative = DILATED IVC. 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)	12 Feb 2021 12:35:26
User opened query 'Per DM CLR: Narrative = MULTIPLE CARDIOVERSIONS AND ABLATION IN 2012. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:35:20

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Jan 2021 16:07:04
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'will send d/c summary 22jan2021' (Site from Safety).	Sandra Clancy (b) (4)	22 Jan 2021 00:54:00
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 15:13:14
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 23:15:32
User entered '73 YEAR OLD WITH HISTORY OF PAF S/P MULTIPLE CARDIOVERSIONS AND ABLATION IN 2012. POST SURGERY HEART RATE IN 120-130S, STABLE BLOOD PRESSURE. ON TTE PERFORMED 21DEC2020, FINDINGS REVEALED PRESERVED LVEF WITH DILATED ATRIA, NO SIGNIFICANT VALVULAR ABNORMALITIES BUT WITH ELEVATED FILLING PRESSURES AND DILATED IVC, CONSISTENT WITH HYPERVOLEMIA; SHE WAS STARTED ON DILTIAZEM AND HAD UNCONTROLLED RATES, THEN GIVEN DIGOXIN WITH NO IMPROVEMENT. SUBSEQUENTLY GIVEN AMIODARONE LOADED AND STARTED ON ESMOLOL.' reason for change: Data Entry Error	Sandra Clancy (b) (4)	28 Dec 2020 18:55:46

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Narrative](#)

Audit	User	Time (GMT)
User entered '73 year old with history of PAF s/p multiple cardioversions and ablation in 2012. Post surgery heart rate in 120-120s, stable blood pressure. On TTE performed 21Dec2020, findings revealed preserved LVEF with dilated atria, no significant valvular abnormalities but with elevated filling pressures and dilated IVC, consistent with hypervolemia; she was started on diltiazem and had uncontrolled rates, then given digoxin with no improvement. Subsequently given amiodarone loaded and started on esmolol.'	Sandra Clancy (b) (4)	28 Dec 2020 18:51:01

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Dec 2020 18:51:01

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Dec 2020 18:51:01

US3912121

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:17:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 22:20:27
User entered '0'	System	28 Dec 2020 18:51:01

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:13:01
User coded data point as SOC: Cardiac disorders, HLT: Myocardial disorders, HLT: Myocardial disorders NEC, PT: Left atrial enlargement, LLT: Left atrial enlargement - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 17:52:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Jan 2021 17:52:57
Data point term sent to Coder	System	11 Jan 2021 20:08:26
User entered 'left atrium dilation'	Sandra Clancy (b) (4)	11 Jan 2021 20:08:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '21 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4)	11 Jan 2021 20:08:01
	(b) (4)	

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4)	11 Jan 2021 20:08:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4)	11 Jan 2021 20:08:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4)	11 Jan 2021 20:08:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4)	11 Jan 2021 20:08:01
	(b) (4)	

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4)	11 Jan 2021 20:08:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'Not Applicable (NOT APPLICABLE)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'I'	Sandra Clancy (b) (4)	11 Jan 2021 20:08:01
	(b) (4)	

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User closed query 'Per DM CLR: Narrative = TRANSTHORACIC ECHOCARDIOGRAM WAS PERFORMED ON 21DEC2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:03:17
Query 'Per DM CLR: Narrative = TRANSTHORACIC ECHOCARDIOGRAM WAS PERFORMED ON 21DEC2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:47:37
User opened query 'Per DM CLR: Narrative = TRANSTHORACIC ECHOCARDIOGRAM WAS PERFORMED ON 21DEC2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:35:49
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'DURING THE HOSPITALIZATION OF THIS SUBJECT, SHE WAS EVALUATED FOR POSSIBLE POST-OP STROKE. A TRANSTHORACIC ECHOCARDIOGRAM WAS PERFORMED ON 21DEC2020 which revealed findings of 'severely dilated left atrium'.' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:09:51
User entered 'During the hospitalization of this subject, she was evaluated for possible post-op stroke. A transthoracic echocardiogram was performed on 21Dec2020 and this was a finding.'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Jan 2021 20:08:01

US3912121

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:17:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Jan 2021 20:08:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:58:59
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'subject had SARSCOV2 test on 18Dec2020 with negative results' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:49:38
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:56:04
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:13:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 20:19:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 20:19:41
Data point term sent to Coder	System	11 Jan 2021 20:18:35
User entered 'right pleural effusion'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '18 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User entered empty.	System	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '21 Dec 2020'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User entered empty.	System	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'Not Related (NOT RELATED)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'Not Applicable (NOT APPLICABLE)'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'l'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered '0'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 20:18:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 20:18:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:18:06
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 20:17:57
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered empty.	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User closed query 'Per DM CLR: Narrative = CT PERFORMED ON 18DEC2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 17:59:27
Query 'Per DM CLR: Narrative = CT PERFORMED ON 18DEC2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:49:50
User opened query 'Per DM CLR: Narrative = CT PERFORMED ON 18DEC2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 12:36:04
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:13:01
User entered 'This finding was documented on the CT performed on 18Dec2020; there does not appear to be any follow up otherwise during the hospitalization.'	Sandra Clancy (b) (4) (b) (4)	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User entered '0'	System	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48
User entered 'I'	System	11 Jan 2021 20:17:57

US3912121

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:17:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:17:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:13:34
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:58:29

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: SOTALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 17:00:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 17:00:52
Data point term sent to Coder	System	13 Sep 2020 16:59:49
User entered 'sotalol'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'atrial fibrillation'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '80'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'twice daily (BID)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Oral (ORAL)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'UN UNK 2011'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Jan 2021 22:45:37
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '28 Dec 2020' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Jan 2021 22:45:37
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User entered '2'	System	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User entered '1'	System	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:02
User entered '804 (804)'	System	13 Sep 2020 16:59:30

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 17:02:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 17:02:53
	(b) (4)	
Data point term sent to Coder	System	13 Sep 2020 17:01:51
User entered 'synthroid'	Tina Rountree (b) (4)	13 Sep 2020 17:00:57
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4)	13 Sep 2020 17:00:57
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'hypothyroidism'	Tina Rountree (b) (4)	13 Sep 2020 17:00:57
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '150'	Tina Rountree (b) (4)	13 Sep 2020 17:00:57
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:00:57

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4)	13 Sep 2020 17:00:57
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'twice daily (BID)'	Tina Rountree (b) (4)	13 Sep 2020 17:00:57
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4)	13 Sep 2020 17:00:57
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	13 Sep 2020 17:00:57
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4)	13 Sep 2020 17:00:57
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'UN UNK 1984'	Tina Rountree (b) (4)	13 Sep 2020 17:00:57
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '0'	Tina Rountree (b) (4)	13 Sep 2020 17:00:57
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Yes (Y)'	Tina Rountree (b) (4)	13 Sep 2020 17:00:57
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:00:57

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4)	13 Sep 2020 17:00:57
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Sep 2020 17:00:57

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 17:00:57

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Sep 2020 17:00:57

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 17:04:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 17:04:53
	(b) (4)	
Data point term sent to Coder	System	13 Sep 2020 17:03:51
User entered 'Eloquist'	Tina Rountree (b) (4)	13 Sep 2020 17:03:14
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:03:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'atrial fibrillation'	Tina Rountree (b) (4)	13 Sep 2020 17:03:14
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '5'	Tina Rountree (b) (4)	13 Sep 2020 17:03:14
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:03:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4)	13 Sep 2020 17:03:14
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'twice daily (BID)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:03:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:03:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	13 Sep 2020 17:03:14
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:03:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'UN UNK 2011'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:03:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '0'	Tina Rountree (b) (4)	13 Sep 2020 17:03:14
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:03:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:03:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4)	13 Sep 2020 17:03:14
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Sep 2020 17:03:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 17:03:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Sep 2020 17:03:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTROGENS CONJUGATED, PRODUCTSYNONYM: PREMARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:02:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 15:02:39
Data point term sent to Coder	System	03 Oct 2020 15:01:30
Coding entries removed.	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:00:34
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTROGENS CONJUGATED, PRODUCTSYNONYM: PREMARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 04:50:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 04:50:38
Data point term sent to Coder	System	13 Sep 2020 17:05:51
User entered 'premarin'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:05:25

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4)	13 Sep 2020 17:05:25
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'hormone replacement'	Tina Rountree (b) (4)	13 Sep 2020 17:05:25
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '.9'	Tina Rountree (b) (4)	13 Sep 2020 17:05:25
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'mg (mg)'	Tina Rountree (b) (4)	13 Sep 2020 17:05:25
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4)	13 Sep 2020 17:05:25
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'once daily (QD)'	Tina Rountree (b) (4)	13 Sep 2020 17:05:25
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4)	13 Sep 2020 17:05:25
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Oct 2020 15:00:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Oct 2020 15:00:34
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	03 Oct 2020 15:00:34
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Sep 2020 17:05:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:05:25

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4)	13 Sep 2020 17:05:25
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'UN UNK 1984'	Tina Rountree (b) (4)	13 Sep 2020 17:05:25
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '0'	Tina Rountree (b) (4)	13 Sep 2020 17:05:25
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Yes (Y)'	Tina Rountree (b) (4)	13 Sep 2020 17:05:25
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4)	13 Sep 2020 17:05:25
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4)	13 Sep 2020 17:05:25
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 17:05:25

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 17:05:25

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Sep 2020 17:05:25

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
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)	13 Sep 2020 17:08:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 17:08:54
Data point term sent to Coder	System	13 Sep 2020 17:07:54
User entered 'amlodipine'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered 'hypertension'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered '5'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered 'twice daily (BID)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered 'Oral (ORAL)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered 'UN UNK 2015'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered '0'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered 'No (N)' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Jan 2021 22:50:06
User entered 'Yes (Y)'	(b) (4) Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered '28 Dec 2020' reason for change: Data Entry Error	Tina Rountree (b) (4)	14 Jan 2021 22:50:06
User entered empty.	(b) (4) Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:44
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User entered '2'	System	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User entered '1'	System	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:11
User entered '804 (804)'	System	13 Sep 2020 17:06:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL ARTHRITIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 17:08:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Sep 2020 17:08:53
Data point term sent to Coder	System	13 Sep 2020 17:07:52
User entered 'tylenol arthritis'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:07:47

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:07:47

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'arthritis'	Tina Rountree (b) (4)	13 Sep 2020 17:07:47
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'I'	Tina Rountree (b) (4)	13 Sep 2020 17:07:47
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'tablet (TABLET)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:07:47

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:07:47

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'three times daily (TID)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:07:47

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:07:47

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Oral (ORAL)'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:07:47

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:07:47

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'UN UNK 2015'	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:07:47

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '0'	Tina Rountree (b) (4)	13 Sep 2020 17:07:47
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Sep 2020 17:08:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Sep 2020 17:08:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:08:24
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Sep 2020 17:07:47
User entered empty.	Tina Rountree (b) (4) (b) (4)	13 Sep 2020 17:07:47

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4)	13 Sep 2020 17:07:47
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4)	13 Sep 2020 17:07:47
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Sep 2020 17:07:47

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Sep 2020 17:07:47

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Sep 2020 17:07:47

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:42:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:42:52
Data point term sent to Coder	System	28 Oct 2020 16:25:42
User entered 'Influenza Vaccine'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Yes (Y)'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Flu prevention'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'l'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Other (OTHER)'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Injection'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'once (ONCE)'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Intramuscular (INTRAMUSCULAR)'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '21 Oct 2020'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '0'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '21 Oct 2020'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Mia Rountree (b) (4) (b) (4)	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User entered empty.	System	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User entered empty.	System	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:22
User entered empty.	System	28 Oct 2020 16:25:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE, PRODUCTSYNONYM: PHENERGAN [PROMETHAZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 09:53:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 09:53:49
Data point term sent to Coder	System	14 Jan 2021 22:55:52
User entered 'Phenergan'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered 'Small BowI Obstruction'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered '6.25'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered 'as needed (PRN)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered '18 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered '25 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:35
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User entered empty.	System	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User entered empty.	System	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:32
User entered empty.	System	14 Jan 2021 22:55:02

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 01:41:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 01:41:00
Data point term sent to Coder	System	14 Jan 2021 22:59:56
User entered 'Morphine'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered 'Small bowel obstruction'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered '2'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered 'as needed (PRN)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered '18 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered '25 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:36
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User entered empty.	System	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User entered empty.	System	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:40
User entered empty.	System	14 Jan 2021 22:59:36

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
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)	11 Mar 2021 16:27:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Mar 2021 16:27:54
Data point term sent to Coder Coding entries removed.	System Sandra Clancy (b) (4)	10 Mar 2021 22:26:57 10 Mar 2021 22:26:21
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:19:25
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)	14 Jan 2021 23:06:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 23:06:59
Data point term sent to Coder User entered 'Cefepime'	System Tina Rountree (b) (4)	14 Jan 2021 23:02:58 14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:21:17
User closed query 'Per DM: Re query: Response noted. Kindly update the indication as Infection Prophylaxis. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:40:05
Query 'Per DM: Re query: Response noted. Kindly update the indication as Infection Prophylaxis. Thank you.' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 22:26:30
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 22:26:21
User entered 'INFECTION prophylaxis' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 22:26:21
User opened query 'Per DM: Re query: Response noted. Kindly update the indication as Infection Prophylaxis. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 18:11:53
User closed query 'Per DM CLR: Please note, Prophylaxis =Yes. Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for post bowel resection, etc.). Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	26 Feb 2021 18:11:53
' (Site from DM).		
Query 'Per DM CLR: Please note, Prophylaxis =Yes. Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for post bowel resection, etc.). Update Con Med eCRF as appropriate.	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:53:30
' answered with 'condition is correct - use is for infection prophylaxis' (Site from DM).		
User opened query 'Per DM CLR: Please note, Prophylaxis =Yes. Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for post bowel resection, etc.). Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	15 Feb 2021 09:33:19
' (Site from DM).		

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for post bowel resection). Update Con Med eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 09:12:20
User opened query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for post bowel resection). Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	15 Feb 2021 09:11:54
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Infection'	Tina Rountree (b) (4)	14 Jan 2021 23:02:13
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '1000'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'once (ONCE)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '18 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '18 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User entered empty.	System	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User entered empty.	System	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:20:50
User entered empty.	System	14 Jan 2021 23:02:13

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:13:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:13:28
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 01:27:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 01:27:00
Data point term sent to Coder	System	14 Jan 2021 23:07:00
User entered 'Metoprolol'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:06:23

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:06:23

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'paroxysmal a-fib'	Tina Rountree (b) (4)	14 Jan 2021 23:06:23
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '5'	Tina Rountree (b) (4)	14 Jan 2021 23:06:23
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:06:23

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4)	14 Jan 2021 23:06:23
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'once daily (QD)'	Tina Rountree (b) (4)	14 Jan 2021 23:06:23
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4)	14 Jan 2021 23:06:23
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:06:23

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4)	14 Jan 2021 23:06:23
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '18 Dec 2020'	Tina Rountree (b) (4)	14 Jan 2021 23:06:23
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '0'	Tina Rountree (b) (4)	14 Jan 2021 23:06:23
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4)	14 Jan 2021 23:06:23
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '22 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:06:23

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:06:23

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 23:06:23

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 23:06:23

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Jan 2021 23:06:23

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:14:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:14:59
Data point term sent to Coder	System	14 Jan 2021 23:11:01
User entered 'Diltiazem'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'hypertension'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '20'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'once daily (QD)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening Hypertension should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:22:35
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening Hypertension should be recorded, and update con med indication or provide clarification. ' answered with 'given as part of her routine treatment; the route is different due to the fact the subject is under sedation.' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:05:42
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening Hypertension should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 10:14:17
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '18 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '19 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User entered '1'	System	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User entered '1'	System	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:33
User entered '804 (804)'	System	14 Jan 2021 23:10:16

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 09:54:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 09:54:24
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:17:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 09:54:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 09:54:48
Data point term sent to Coder	System	14 Jan 2021 23:13:02
User entered 'Potassium Chloride'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:17:39
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:23:05
(Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	Sandra Clancy (b) (4)	25 Feb 2021 01:06:30
' answered with 'it is part of subject's hospital course; it is not an AE.' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4), (b) (6)	15 Feb 2021 10:32:25
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'hyperkalemia'	Tina Rountree (b) (4)	14 Jan 2021 23:12:06
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '20'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Other (OTHER)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'mEq'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'once daily (QD)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '19 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered '27 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:19:25
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User entered '1'	System	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User entered '1'	System	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:51:18
User entered '804 (804)'	System	14 Jan 2021 23:12:06

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC GLYCOSIDES, ATC: DIGITALIS GLYCOSIDES, PRODUCT: DIGOXIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:17:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:17:59
Data point term sent to Coder	System	14 Jan 2021 23:16:05
User entered 'Digoxin'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered 'paroxysmal a-fib'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered '0.5'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered 'once daily (QD)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered '19 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered '19 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:46
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User entered '1'	System	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User entered '1'	System	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:44
User entered '804 (804)'	System	14 Jan 2021 23:15:14

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:17:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:17:59
Data point term sent to Coder	System	14 Jan 2021 23:17:05
User entered 'Melatonin'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:24:44
' (Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:07:51
' answered with 'correct, no AE; this subject has had emergent surgery and this event is part of the subject's hospital course' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.	(b) (4), (b) (6)	15 Feb 2021 10:56:24
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered 'Insomnia'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered '3'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered 'as needed (PRN)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered 'Oral (ORAL)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered '20 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered '26 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:47
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User entered empty.	System	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User entered empty.	System	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:21:55
User entered empty.	System	14 Jan 2021 23:16:39

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
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)	14 Jan 2021 23:19:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:19:59
Data point term sent to Coder	System	14 Jan 2021 23:19:09
User entered 'Trazodone'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:26:11
' (Site from DM). Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:08:40
' answered with 'correct - part of main AE of small bowel obstruction requiring emergent surgery' (Site from DM). User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4), (b) (6)	15 Feb 2021 10:56:34
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered 'insomnia'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered '50'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered 'as needed (PRN)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered 'Oral (ORAL)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered '20 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered '27 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:49
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User entered empty.	System	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User entered empty.	System	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:20
User entered empty.	System	14 Jan 2021 23:18:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:51
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)	14 Jan 2021 23:20:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:20:58
Data point term sent to Coder	System	14 Jan 2021 23:20:10
User entered 'Lovenox'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:02
DataPoint Un-verified.	Sandra Clancy (b) (4)	25 Feb 2021 01:11:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Sandra Clancy (b) (4)	25 Feb 2021 01:11:37
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User closed query 'Per DM CLR: Indication = Prophylaxis. However, Prophylaxis is No. Update Con Med eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:30:19
Query 'Per DM CLR: Indication = Prophylaxis. However, Prophylaxis is No. Update Con Med eCRF as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:11:43
User opened query 'Per DM CLR: Indication = Prophylaxis. However, Prophylaxis is No. Update Con Med eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 10:57:02
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered 'clot prevention'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 09:43:59
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'data correct, clarified with subject and data correct in medical records from hospital' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 03:04:27
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 12:46:45
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered '70'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered 'as needed (PRN)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered 'Subcutaneous (SUBCUTANEOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered '21 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered '27 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:51
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User entered empty.	System	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User entered empty.	System	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:26
User entered empty.	System	14 Jan 2021 23:19:51

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: OLANZAPINE, PRODUCTSYNONYM: ZYPREXA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:24:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:24:00
Data point term sent to Coder	System	14 Jan 2021 23:23:11
User entered 'Zyprexa'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:32:48
(Site from DM).		
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:21:14
' answered with 'subject had a transient episode of altered mental status and she was worked up for post-op stroke. but the findings were negative for stroke. there is really no other notation for why this occurred.' (Site from DM).		
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.'	(b) (4), (b) (6)	15 Feb 2021 11:00:04
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered 'post-op altered mental status'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered '5'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered 'once daily (QD)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered '21 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered '21 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:53
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User entered '1'	System	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User entered '1'	System	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:34
User entered '804 (804)'	System	14 Jan 2021 23:22:21

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:05:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:05:12
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	28 Mar 2021 16:23:10
Data point term sent to Coder	System	26 Mar 2021 20:34:18
Coding entries removed.	(b) (4), (b) (6)	26 Mar 2021 20:34:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 07:39:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 07:39:09
Data point term sent to Coder	System	25 Feb 2021 01:24:25
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:23:42
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:14:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:26:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:26:59
Data point term sent to Coder	System	14 Jan 2021 23:24:13
User entered 'Furosemide'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:55:15
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mark Hutchens (b) (4)	29 Mar 2021 10:06:32 28 Mar 2021 16:23:10
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'This conmed was given to subject in hosiptal post-op small bowel obstruction' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:34:27
DataPoint Un-verified.	(b) (4), (b) (6)	26 Mar 2021 20:34:13
User entered 'SMall bowel obstruction' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 20:34:13
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 12:46:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:42:11
DataPoint Un-verified.	Sandra Clancy (b) (4)	25 Feb 2021 01:23:42
User entered 'Hypervolemia' reason for change: Data Entry Error	Sandra Clancy (b) (4)	25 Feb 2021 01:23:42
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered 'hypertension'	Tina Rountree (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered '20'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered 'as needed (PRN)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening Hypertension should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:33:36
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening Hypertension should be recorded, and update con med indication or provide clarification. ' answered with 'subject had fluid overload and was diuresed with lasix (furosemide)' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:25:09
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening Hypertension should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:04:56
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered '22 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered '24 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:56
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User entered empty.	System	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User entered empty.	System	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:22:44
User entered empty.	System	14 Jan 2021 23:23:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 11:13:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 11:13:04
Data point term sent to Coder	System	25 Feb 2021 01:27:27
Coding entries removed.	Sandra Clancy (b) (4)	25 Feb 2021 01:27:26
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:14:59
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 23:28:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 23:28:00
Data point term sent to Coder	System	14 Jan 2021 23:27:15
User entered 'Levothyroxine'	Tina Rountree (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:59
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication (HYPOTHYROIDISM). Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:06:44
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication (HYPOTHYROIDISM). Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'data updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:40:41
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication (HYPOTHYROIDISM). Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 12:48:05
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:42:18
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:38:55
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF.' answered with 'see med history' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:27:37
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:27:26
User entered 'HYPOTHYROIDISM post thyroidectomy' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:27:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 11:09:32
	(b) (4), (b) (6)	21 Jan 2021 21:14:59
User entered 'hypothyroidism'	Tina Rountree (b) (4)	14 Jan 2021 23:26:48
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:59
User entered '75'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:18
User closed query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'MCG'. However, instead of entering Other-MCG, if appropriate please consider selecting 'µg' from available options in Dose unit field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:38:57
Query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'MCG'. However, instead of entering Other-MCG, if appropriate please consider selecting 'µg' from available options in Dose unit field. Thank you. ' answered with 'corrected' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:28:27
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:28:19
User entered 'ug (ug)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:28:19
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:14:59
User opened query 'Per CDM: Dose unit was recorded as Other and If dose unit is Other, specify was recorded as 'MCG'. However, instead of entering Other-MCG, if appropriate please consider selecting 'µg' from available options in Dose unit field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 10:02:47
User entered 'Other (OTHER)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:18
DataPoint Un-verified.	Sandra Clancy (b) (4)	25 Feb 2021 01:28:19
User entered empty; reason for change Data Entry Error	(b) (4) Sandra Clancy (b) (4)	25 Feb 2021 01:28:19
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:14:59
User entered 'mcg'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:59
User entered 'once daily (QD)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:59
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:59
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:59
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:59
User entered '23 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:59
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:59
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:59
User entered '27 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:14:59
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User entered '1'	System	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User entered '1'	System	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:23:46
User entered '804 (804)'	System	14 Jan 2021 23:26:48

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 01:31:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 01:31:05
Data point term sent to Coder	System	25 Feb 2021 01:30:30
Coding entries removed.	Sandra Clancy (b) (4)	25 Feb 2021 01:29:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:15:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 23:29:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 23:29:58
Data point term sent to Coder	System	14 Jan 2021 23:29:16
User entered 'acetaminophen'	Tina Rountree (b) (4)	14 Jan 2021 23:29:10
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:24
User closed query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 18:36:18
Query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:29:46
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:29:39
User entered 'post surgery - small bowel obstruction' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:29:39
User opened query 'Per DM CLR: Please note there is no ongoing AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:11:21
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered 'pain d/c small bowel obstruction'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered '650'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered 'as needed (PRN)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered 'Oral (ORAL)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered '26 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered '26 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:02
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User entered empty.	System	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User entered empty.	System	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:06
User entered empty.	System	14 Jan 2021 23:29:10

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ESMOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:33:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:33:59
Data point term sent to Coder	System	14 Jan 2021 23:31:18
User entered 'Esmolol'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered 'paroxysmal a-fib'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered '2500'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered 'once daily (QD)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered '20 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered '25 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:05
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User entered '1'	System	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User entered '1'	System	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:14
User entered '804 (804)'	System	14 Jan 2021 23:30:49

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: AMINO ACIDS NOS;GLUCOSE;LIPIDS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 08:45:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 08:45:32
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:43:13
Data point term sent to Coder	System	25 Feb 2021 01:41:40
User closed query 'For coding purposes, the reported trade name cannot be referenced in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' (Site from System).	System	25 Feb 2021 01:41:21
Query 'For coding purposes, the reported trade name cannot be referenced in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' answered with 'other than what has been provided, there is not any other description of ingredients' (Site from System).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:41:21
Data point term sent to Coder	System	25 Feb 2021 01:40:39
DataPoint Un-verified.	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:40:31
User entered 'TPN ADULT (AMINO ACID/DEXTROSE SOLUTION AND A LIPID EMULSION)' reason for change: Data Entry Error	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:40:31
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:15:09

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, the reported trade name cannot be referenced in the standard coding dictionary. Please enter the active ingredient(s) in parenthesis after drug name and please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	15 Jan 2021 17:47:55
Data point term sent to Coder	System	14 Jan 2021 23:34:25
User entered 'TPN Adult'	Tina Rountree (b) (4)	14 Jan 2021 23:33:54
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User closed query 'PER CDM: Indication for the medication was recorded as 'NUTRITIONAL SUPPORT'. However, prophylaxis was recorded as NO. Per CCG V5.0 Page 53, If taken as prophylaxis*, we recommend reporting as "Prophylaxis for...". "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 07:43:45
Query 'PER CDM: Indication for the medication was recorded as 'NUTRITIONAL SUPPORT'. However, prophylaxis was recorded as NO. Per CCG V5.0 Page 53, If taken as prophylaxis*, we recommend reporting as "Prophylaxis for...". "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Please review and update as appropriate. Thank you.' answered with 'it was not prophylaxis - entry correct as is' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 22:27:41
User opened query 'PER CDM: Indication for the medication was recorded as 'NUTRITIONAL SUPPORT'. However, prophylaxis was recorded as NO. Per CCG V5.0 Page 53, If taken as prophylaxis*, we recommend reporting as "Prophylaxis for...". "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 07:20:37
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:40:13
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:41:55
' answered with 'this is part of the subject's hospital course post-op' (Site from DM).		
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	15 Feb 2021 11:13:31
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered 'nutritional support'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered '1680'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered 'mL (mL)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered 'once daily (QD)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered '21 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered '28 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:09
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User entered '1'	System	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User entered '1'	System	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:52:08
User entered '804 (804)'	System	14 Jan 2021 23:33:54

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
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)	14 Jan 2021 23:42:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:42:59
Data point term sent to Coder	System	14 Jan 2021 23:36:26
User entered 'Amiodarone'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered 'paroxysmal a-fib'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered '450'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered 'once daily (QD)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered '21 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered '27 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:11
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User entered '1'	System	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User entered '1'	System	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:24:29
User entered '804 (804)'	System	14 Jan 2021 23:35:53

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:14
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)	14 Jan 2021 23:43:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:43:58
Data point term sent to Coder	System	14 Jan 2021 23:38:27
User entered 'Amiodarone'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:38:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:38:00

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered 'paroxysmal a-fib'	Tina Rountree (b) (4)	14 Jan 2021 23:38:00
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered '400'	Tina Rountree (b) (4)	14 Jan 2021 23:38:00
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered 'mg (mg)'	Tina Rountree (b) (4)	14 Jan 2021 23:38:00
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered empty.	Tina Rountree (b) (4)	14 Jan 2021 23:38:00
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered 'once daily (QD)'	Tina Rountree (b) (4)	14 Jan 2021 23:38:00
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered empty.	Tina Rountree (b) (4)	14 Jan 2021 23:38:00
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered 'Oral (ORAL)'	Tina Rountree (b) (4)	14 Jan 2021 23:38:00
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered empty.	Tina Rountree (b) (4)	14 Jan 2021 23:38:00
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered '27 Dec 2020'	Tina Rountree (b) (4)	14 Jan 2021 23:38:00
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered '0'	Tina Rountree (b) (4)	14 Jan 2021 23:38:00
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:45:05
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'this medication is used to maintain normal rhythm and keep the subject out of atrial fibrillation' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:43:17
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:14:14
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:38:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered empty.	Tina Rountree (b) (4)	14 Jan 2021 23:38:00
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

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[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 21:15:14
User entered 'No (N)'	Tina Rountree (b) (4)	14 Jan 2021 23:38:00
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 23:38:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 23:38:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Jan 2021 23:38:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 05:01:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 05:01:42
Data point term sent to Coder	System	05 Apr 2021 14:58:10
Coding entries removed.	Mia Rountree (b) (4) (b) (4)	05 Apr 2021 14:57:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:08:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 07:08:07
User signature succeeded.	Mark Hutchens (b) (4) (b) (4)	28 Mar 2021 16:23:10
Data point term sent to Coder	System	26 Mar 2021 20:36:21
Coding entries removed.	(b) (4), (b) (6)	26 Mar 2021 20:35:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 16:42:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 16:42:52
Data point term sent to Coder	System	10 Mar 2021 22:32:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Sandra Clancy (b) (4)	10 Mar 2021 22:31:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Feb 2021 13:38:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 13:38:12
Data point term sent to Coder	System	25 Feb 2021 01:44:41
Coding entries removed.	Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 01:44:08
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:15:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:39:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:39:58
Data point term sent to Coder	System	14 Jan 2021 23:39:28
User entered 'Cefepime'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
User closed query 'PER CDM: Prophylaxis was recorded as YES. Per CCG V5.0 Page 53, If taken as prophylaxis*, we recommend reporting as "Prophylaxis for...". "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 07:44:08
Query 'PER CDM: Prophylaxis was recorded as YES. Per CCG V5.0 Page 53, If taken as prophylaxis*, we recommend reporting as "Prophylaxis for...". "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Please review and update as appropriate. Thank you. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4) (b) (4)	10 Mar 2021 22:31:16
User opened query 'PER CDM: Prophylaxis was recorded as YES. Per CCG V5.0 Page 53, If taken as prophylaxis*, we recommend reporting as "Prophylaxis for...". "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 07:21:49
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:06:51
User signature succeeded.	Mark Hutchens (b) (4)	06 Apr 2021 15:47:13
User closed query 'PER CDM: Prophylaxis was recorded as YES. Per CCG V5.0 Page 53, If taken as prophylaxis*, we recommend reporting as "Prophylaxis for...". "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:47:19
Query 'PER CDM: Prophylaxis was recorded as YES. Per CCG V5.0 Page 53, If taken as prophylaxis*, we recommend reporting as "Prophylaxis for...". "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Please review and update as appropriate. Thank you. ' answered with 'Data updated' (Site from DM).	Mia Rountree (b) (4) (b) (4)	05 Apr 2021 14:57:37
DataPoint Un-verified.	Mia Rountree (b) (4) (b) (4)	05 Apr 2021 14:57:15
Signature has been broken.	Mia Rountree (b) (4) (b) (4)	05 Apr 2021 14:57:15
User entered 'Prophylaxis for SMALL BOWEL OBSTRUCTION' reason for change: Data Entry Error	Mia Rountree (b) (4) (b) (4)	05 Apr 2021 14:57:15
User opened query 'PER CDM: Prophylaxis was recorded as YES. Per CCG V5.0 Page 53, If taken as prophylaxis*, we recommend reporting as "Prophylaxis for...". "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 10:20:17
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:45

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

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[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	29 Mar 2021 10:07:29
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'This conmed was given to subject in hosiptal post-op small bowel obstruction' (Site from DM). DataPoint Un-verified.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'This conmed was given to subject in hosiptal post-op small bowel obstruction' (Site from DM). DataPoint Un-verified.	(b) (4)	
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'This conmed was given to subject in hosiptal post-op small bowel obstruction' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	26 Mar 2021 20:35:32
User entered 'Small bowel obstruction' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 20:35:25
User entered 'Small bowel obstruction' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 20:35:25
User entered 'Small bowel obstruction' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:31
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 12:48:32
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). DataPoint Un-verified.	Sandra Clancy (b) (4)	10 Mar 2021 22:31:08
User entered 'prophylaxis for post op INFECTION' reason for change: Data Entry Error DataPoint Verified.	(b) (4)	
User entered 'prophylaxis for post op INFECTION' reason for change: Data Entry Error DataPoint Verified.	Sandra Clancy (b) (4)	10 Mar 2021 22:31:08
User entered 'prophylaxis for post op INFECTION' reason for change: Data Entry Error DataPoint Verified.	(b) (4)	
User entered 'prophylaxis for post op INFECTION' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 20:42:40
User closed query 'Per DM CLR: Please note, Prophylaxis=Yes. Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for post bowel resection, etc.). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 18:46:37
Query 'Per DM CLR: Please note, Prophylaxis=Yes. Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for post bowel resection, etc.). Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	Sandra Clancy (b) (4)	25 Feb 2021 01:44:17
Query 'Per DM CLR: Please note, Prophylaxis=Yes. Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for post bowel resection, etc.). Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Sandra Clancy (b) (4)	25 Feb 2021 01:44:08
	(b) (4)	
User entered 'INFECTION - post op' reason for change: Data Entry Error	Sandra Clancy (b) (4)	25 Feb 2021 01:44:08
	(b) (4)	
User opened query 'Per DM CLR: Please note, Prophylaxis=Yes. Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for post bowel resection, etc.). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 11:18:33
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered 'infection'	Tina Rountree (b) (4)	14 Jan 2021 23:39:24
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered '2000'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered 'once daily (QD)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered '20 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered '25 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:17
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:39:24

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User entered '1'	System	14 Jan 2021 23:39:24

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User entered '1'	System	14 Jan 2021 23:39:24

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:34
User entered '804 (804)'	System	14 Jan 2021 23:39:24

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC GLYCOSIDES, ATC: DIGITALIS GLYCOSIDES, PRODUCT: DIGOXIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:42:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 23:42:58
Data point term sent to Coder	System	14 Jan 2021 23:41:31
User entered 'digoxin'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered 'paroxysmal a-fib'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered '0.125'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered 'mg (mg)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered 'once daily (QD)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered 'Intravenous (INTRAVENOUS)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered empty.	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered '21 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered '0'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered '25 Dec 2020'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 21:15:21
User entered 'No (N)'	Tina Rountree (b) (4) (b) (4)	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User entered '1'	System	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User entered '1'	System	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:25:43
User entered '804 (804)'	System	14 Jan 2021 23:40:40

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: SOTALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 17:19:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 17:19:35
Data point term sent to Coder	System	09 Feb 2021 17:18:22
User entered 'sotolol'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'No (N)'	Sandra Clancy (b) (4)	09 Feb 2021 17:17:41
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'atrial fibrillation'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered '80'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'twice daily (BID)'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4)	09 Feb 2021 17:17:41
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered '27 Jan 2021'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered '0'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Feb 2021 17:17:41

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
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)	09 Feb 2021 17:20:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 17:20:36
Data point term sent to Coder	System	09 Feb 2021 17:19:23
User entered 'amlodipine'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'hypertension'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered '5'	Sandra Clancy (b) (4)	09 Feb 2021 17:18:26
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'mg (mg)'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'once daily (QD)'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'Oral (ORAL)'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered '27 Jan 2021'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered '0'	Sandra Clancy (b) (4)	09 Feb 2021 17:18:26
	(b) (4)	

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'Yes (Y)'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered empty.	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	28 Mar 2021 16:23:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:42:51
User entered 'No (N)'	Sandra Clancy (b) (4) (b) (4)	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 10:17:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Feb 2021 17:18:26

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:17:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:00:56
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:52:18
User entered 'Yes (Y)'	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:53:49

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:17:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:52:34
User entered '18 Dec 2020'	Tina Rountree (b) (4)	19 Dec 2020 21:55:14
	(b) (4)	

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:17:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:52:34
User entered 'Bowel Resection'	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:55:14

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:52:34
User entered 'Adverse Event (AE)'	Tina Rountree (b) (4) (b) (4)	19 Dec 2020 21:55:14

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:17:58

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:52:34
User entered empty.	Tina Rountree (b) (4)	19 Dec 2020 21:55:14
	(b) (4)	

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:17:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:03
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '18 Dec 2020'	(b) (4) Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 23:58:57

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:17:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:03
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'CT abdomen/pelvis with contrast'	(b) (4) Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 23:58:57

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:03
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 23:58:57

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:17:58

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:03
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 23:58:57

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:17:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:06
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '18 Dec 2020'	(b) (4) Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 23:59:40

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:17:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:06
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'X-ray chest'	(b) (4) Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 23:59:40

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:06
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 23:59:40

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:17:58

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:28
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:06
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	24 Feb 2021 23:59:40

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:17:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '18 Dec 2020'	(b) (4) Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:01:14

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:17:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Electrocardiogram'	(b) (4) Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:01:14

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:01:14

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:17:58

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:32
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:10
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:01:14

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:17:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:13
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '21 Dec 2020'	(b) (4) Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:47:05

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:17:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:13
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'transthoracic echocardiogram'	(b) (4) Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:47:05

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:17:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:13
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:47:05

US3912121

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:17:58

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 18:54:13
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered empty.	(b) (4) Sandra Clancy (b) (4) (b) (4)	25 Feb 2021 00:47:05

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:25
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered	System	21 Dec 2020 14:17:12
'USA-US211-2020-MRNA-1273-P301000009'		

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	21 Dec 2020 19:38:24
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:20
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:19
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:14
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:44
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	System	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Mark'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:12
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Timothy'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:45
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	(b) (4)	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Hutchens'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	21 Dec 2020 19:38:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Vachris'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:08
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:55
User entered 'US'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered '7'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
	(b) (4)	
User entered '6'	System	26 Jan 2021 15:39:50
User entered '5'	System	22 Jan 2021 16:07:35
User entered '4'	System	05 Jan 2021 15:33:29
User entered '3'	System	29 Dec 2020 14:15:06
User entered '2'	System	23 Dec 2020 15:37:48
User entered '1'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:25
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered		
'USA-US211-2020-MRNA-1273-P301000009'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:24
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:20
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:19
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:14
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:44
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	System	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Mark'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:38:12
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Timothy'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:45
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	System	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Hutchens'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Vachris'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:08
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:55
User entered 'US'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered '7'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
	(b) (4)	
User entered '6'	System	26 Jan 2021 15:39:50
User entered '5'	System	22 Jan 2021 16:07:35
User entered '4'	System	05 Jan 2021 15:33:29
User entered '3'	System	29 Dec 2020 14:15:06
User entered '2'	System	23 Dec 2020 15:37:48
User entered '1'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:17:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:51:58
User entered '21/Dec/2020 09:17'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:17:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:51:58
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:55
User entered 'I'	(b) (4), (b) (6)	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:25
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'USA-US211-2020-MRNA-1273-P301000009'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:24
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:20
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:19
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:14
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:44
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	System	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Mark'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:38:12
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Timothy'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:45
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	(b) (4)	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Hutchens'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	21 Dec 2020 19:38:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Vachris'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:08
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:55
User entered 'US'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered '7'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
	(b) (4)	
User entered '6'	System	26 Jan 2021 15:39:50
User entered '5'	System	22 Jan 2021 16:07:35
User entered '4'	System	05 Jan 2021 15:33:29
User entered '3'	System	29 Dec 2020 14:15:06
User entered '2'	System	23 Dec 2020 15:37:48
User entered '1'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:17:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:10
User entered '23/Dec/2020 10:37'	System	23 Dec 2020 15:37:48

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:17:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 23:15:10
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 14:14:49
User entered 'I'	(b) (4), (b) (6)	23 Dec 2020 15:37:48

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:25
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered		
'USA-US211-2020-MRNA-1273-P301000009'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:24
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:20
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:19
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:14
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:44
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	System	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Mark'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:38:12
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Timothy'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:45
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	System	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Hutchens'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:38:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Vachris'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:08
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:55
User entered 'US'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered '7'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
	(b) (4)	
User entered '6'	System	26 Jan 2021 15:39:50
User entered '5'	System	22 Jan 2021 16:07:35
User entered '4'	System	05 Jan 2021 15:33:29
User entered '3'	System	29 Dec 2020 14:15:06
User entered '2'	System	23 Dec 2020 15:37:48
User entered '1'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:17:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 23:15:08
User entered '29/Dec/2020 14:14'	System	29 Dec 2020 14:15:06

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:17:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 23:15:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 15:33:07
User entered 'I'	(b) (4), (b) (6)	29 Dec 2020 14:15:06

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:25
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered		
'USA-US211-2020-MRNA-1273-P301000009'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:24
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:20
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:19
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:14
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:44
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	System	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Mark'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:38:12
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Timothy'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:45
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	System	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Hutchens'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Vachris'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:08
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:55
User entered 'US'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered '7'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
	(b) (4)	
User entered '6'	System	26 Jan 2021 15:39:50
User entered '5'	System	22 Jan 2021 16:07:35
User entered '4'	System	05 Jan 2021 15:33:29
User entered '3'	System	29 Dec 2020 14:15:06
User entered '2'	System	23 Dec 2020 15:37:48
User entered '1'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:17:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Jan 2021 23:15:03
User entered '05/Jan/2021 15:33'	System	05 Jan 2021 15:33:29

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:17:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	22 Jan 2021 16:07:15
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 23:15:03
User entered 'I'	(b) (4), (b) (6)	05 Jan 2021 15:33:29

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:25
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'USA-US211-2020-MRNA-1273-P301000009'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:24
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:20
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:19
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:14
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:44
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	System	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Mark'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:38:12
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Timothy'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:45
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	(b) (4)	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Hutchens'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	21 Dec 2020 19:38:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Vachris'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:08
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:55
User entered 'US'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered '7'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
	(b) (4)	
User entered '6'	System	26 Jan 2021 15:39:50
User entered '5'	System	22 Jan 2021 16:07:35
User entered '4'	System	05 Jan 2021 15:33:29
User entered '3'	System	29 Dec 2020 14:15:06
User entered '2'	System	23 Dec 2020 15:37:48
User entered '1'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:17:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:15:13
User entered '22/Jan/2021 16:07'	System	22 Jan 2021 16:07:35

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:17:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 21:15:13
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 15:39:35
User entered 'I'	(b) (4), (b) (6)	22 Jan 2021 16:07:35

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:25
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'USA-US211-2020-MRNA-1273-P301000009'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:24
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:20
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:19
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:14
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:44
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	System	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Mark'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:38:12
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Timothy'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:45
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	(b) (4)	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Hutchens'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	21 Dec 2020 19:38:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Vachris'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:08
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:55
User entered 'US'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered '7'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
	(b) (4)	
User entered '6'	System	26 Jan 2021 15:39:50
User entered '5'	System	22 Jan 2021 16:07:35
User entered '4'	System	05 Jan 2021 15:33:29
User entered '3'	System	29 Dec 2020 14:15:06
User entered '2'	System	23 Dec 2020 15:37:48
User entered '1'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:17:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:15:13
User entered '26/Jan/2021 10:39'	System	26 Jan 2021 15:39:50

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:17:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 18:34:22
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 21:15:13
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 15:39:50

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:25
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered		
'USA-US211-2020-MRNA-1273-P301000009'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:24
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:22
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:20
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:19
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Yes (Y)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:17
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 19:38:14
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'No (N)'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:44
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	System	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Mark'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 19:38:12
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Timothy'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:45
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
Un-reviewed for Safety.	(b) (4)	25 Feb 2021 18:34:43
DataPoint Un-verified.	System	25 Feb 2021 18:34:43
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered 'Hutchens'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	21 Dec 2020 19:38:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:44
User entered 'Vachris'	System	21 Dec 2020 14:17:12

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Dec 2020 19:38:08
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 14:17:55
User entered 'US'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 10:17:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	25 Feb 2021 18:34:43
User entered '7'	System	25 Feb 2021 18:34:43
User signature succeeded.	Mark Hutchens (b) (4)	19 Feb 2021 16:23:43
	(b) (4)	
User entered '6'	System	26 Jan 2021 15:39:50
User entered '5'	System	22 Jan 2021 16:07:35
User entered '4'	System	05 Jan 2021 15:33:29
User entered '3'	System	29 Dec 2020 14:15:06
User entered '2'	System	23 Dec 2020 15:37:48
User entered '1'	System	21 Dec 2020 14:17:51

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:17:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered '25/Feb/2021 13:34'	(b) (4) System	25 Feb 2021 18:34:43

US3912121

Folder: SAE USA-US211-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:17:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:22:51
User signature succeeded.	Mark Hutchens (b) (4)	09 Mar 2021 19:56:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:34:43