

US3512042 (Prod: Jacksonville Center for Clinical Research Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:59:50

All time stamps listed in this document are displayed in GMT

US3512042

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 20:32:20

Generated On: 10 Jun 2021 07:59:50

[Participant ID](#)

US3512042

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

US3512042

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 AUG 2020

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID SCRN

US3512042

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Date of Birth (MMM yyyy)	(b) (6) 1942
Age	78
Age Units	YEARS
Age (Derived)	78
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3512042

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Date of Informed Consent (*dd MMM yyyy*) 12 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

US3512042

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Did the participant meet all eligibility criteria?

Yes

No

US3512042

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	ALLERGY TO SULFA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3512042

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	ALLERGY TO PENICILLIN
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1947
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 1947
Start Year (derived)	1947
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	HEARTBURN
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	GASTRIC ULCER GASTRIC
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	BILATERAL CATARACTS
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	BILATERAL LENS IMPLANT
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 (14)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	BILATERAL HEARING LOSS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	LEFT SIDE OCULAR THROMBOSIS
Start date (dd MMM yyyy)	27 JUN 2016
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)	27 JUN 2016
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JUN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	STROKE
Start date (dd MMM yyyy)	27 JUN 2016
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)	27 JUN 2016
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JUN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	RIGHT HAND TREMOR
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 (18)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	FRACTURE LEFT HIP
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	HIGH BLOOD PRESSURE
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	PAROXYSMAL ATRIAL FIBRILLATION
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)	_____

US3512042

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	ACETABULAR FRACTURE
Start date (dd MMM yyyy)	UN NOV 2019
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 DEC 2019
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	DEC 2019
Stop Year (derived)	2019

US3512042

Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	ACETABULAR SURGERY
Start date (dd MMM yyyy)	UN NOV 2019
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 NOV 2019
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	NOV 2019
Stop Year (derived)	2019

US3512042

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	PELVIC REPAIR SURGERY
Start date (dd MMM yyyy)	08 AUG 2019
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)	08 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

US3512042

Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Screening

Form: Medical History (32)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	BROKEN PELVIS SECONDARY TO FALL
Start date (dd MMM yyyy)	02 AUG 2019
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)	08 AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

US3512042

Folder: Screening

Form: Medical History (33)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Condition	ACETABULAR SURGERY
Start date (dd MMM yyyy)	UN DEC 2019
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 DEC 2019
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	DEC 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:20 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 12:20
Height (<i>xxx.x</i>)	75.0 in
Weight (<i>xxx.x</i>)	177.0 lb
BMI (<i>xxx.x</i>)	22.16974 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) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 20:32:22

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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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 AUG 2020

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 185331

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

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

Height	ND - Not Done
Weight	ND - Not Done

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

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 (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:20 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 12:20
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	54 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

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 (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:58 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 13:58
Temperature (<i>xxx.x</i>)	96.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	53 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3512042

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

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.

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

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) 12 AUG 2020

What was the treatment time? (00:00-23:59) 13:28 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 13:28

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

US3512042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 AUG 2020

Collection time (*00:00-23:59*) 12:58 (24 HR)

Collection date and time (derived) 12 AUG 2020 12:58

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

Collection date (<i>dd MMM yyyy</i>)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:40	12 AUG 2020 12:40
Nasopharyngeal Swab 2	No		

US3512042

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:32:22

Generated On: 10 Jun 2021 07:59:50

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.7 °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 AUG 2020 14:05

PC Open Date & Time 12 AUG 2020 13:48

PC Close Date & Time 12 AUG 2020 16:18

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

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 97.3 °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	12 AUG 2020 17:40
PC Open Date & Time	12 AUG 2020 17:13
PC Close Date & Time	13 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:50

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	13 AUG 2020 16:41
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:50

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 AUG 2020 12:25
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:50

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 AUG 2020 12:28
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:50

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 AUG 2020 15:16
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:50

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 AUG 2020 17:13
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:50

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	18 AUG 2020 14:30
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

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

12 AUG 2020 14:07

PC Open Date & Time

12 AUG 2020 13:48

PC Close Date & Time

12 AUG 2020 16:18

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

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	13 AUG 2020 11:52
PC Open Date & Time	12 AUG 2020 17:13
PC Close Date & Time	13 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

DAY 2

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	13 AUG 2020 16:42
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

DAY 3

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	14 AUG 2020 12:26
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

DAY 4

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

15 AUG 2020 12:29

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

DAY 5

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	16 AUG 2020 15:17
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

DAY 6

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	17 AUG 2020 17:14
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

DAY 7

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	18 AUG 2020 14:31
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

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

No

Yes

PC Time stamp	12 AUG 2020 15:31
PC Open Date & Time	12 AUG 2020 13:48
PC Close Date & Time	12 AUG 2020 16:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

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

No
Yes

PC Time stamp	13 AUG 2020 11:54
PC Open Date & Time	12 AUG 2020 17:13
PC Close Date & Time	13 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:50

	Yes <input type="checkbox"/>
PC Time stamp	13 AUG 2020 16:43
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:50

Yes

PC Time stamp	14 AUG 2020 12:27
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:50

	Yes <input type="checkbox"/>
PC Time stamp	15 AUG 2020 12:30
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:50

	Yes <input type="checkbox"/>
PC Time stamp	16 AUG 2020 15:17
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:50

	Yes <input type="checkbox"/>
PC Time stamp	17 AUG 2020 17:15
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:50

Yes

PC Time stamp	18 AUG 2020 14:31
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3512042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3512042

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3512042

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3512042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:50

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 _____

US3512042

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:50

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3512042

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 07:59:50

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
<hr/>		
<hr/>		

US3512042

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:59:50

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"/>

US3512042

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 07:59:50

Generate Next COVID-19 Assessment

Yes

No

US3512042

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 20:32:20

Generated On: 10 Jun 2021 07:59:50

AEID USA-US065-2020-MRNA-1273-P30
1000001

Adverse event CARDIOPULMONARY ARREST

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) 1 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 1 SEP 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 True

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

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 20:32:20

Generated On: 10 Jun 2021 07:59:50

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
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 20:32:20

Generated On: 10 Jun 2021 07:59:50

PT EXPERIENCED FATAL SAE ON 9/1/2020. HE STOPPED ASA 2-5 DAYS PRIOR TO DEATH IN PREPARATION FOR PLANNED COCHLEAR IMPLANT PROCEDURE ON 9/3/2020. PT HAS HISTORY OF A-FIB, HTN AND HYPERLIPIDEMIA. HE WAS NEGATIVE FOR FEVER, WEIGHT CHANGE, SWELLING. HIS WIFE REPORTED HE WAS SICK ON SUNDAY AND HAD THREE EPISODES OF VOMITING ON 8/31/2020

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)	

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Feb 2021 20:32:20

Generated On: 10 Jun 2021 07:59:50

AEID	
Adverse event	VOMITTING X3
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)	31 AUG 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)	31 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Feb 2021 20:32:20

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Feb 2021 20:32:20

Generated On: 10 Jun 2021 07:59:50

AEID	
Adverse event	MALAISE
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)	30 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Feb 2021 20:32:20

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Feb 2021 20:32:20

Generated On: 10 Jun 2021 07:59:50

AEID	
Adverse event	NAUSEA
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)	30 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Feb 2021 20:32:20

Generated On: 10 Jun 2021 07:59:50

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

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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

Yes

No

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

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Name of Medication ENTERIC ASPIRIN

Prophylaxis Yes
No

Indication POST STROKE

Dose per administration 81

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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 2016

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication OSTEOARTHRITIS HIP

Dose per administration 600

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

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Name of Medication BENADRYL

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

Dose per administration 25

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

	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 2000

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Name of Medication LIPITOR

Prophylaxis Yes
No

Indication HIGH CHOLESTEROL

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

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2010

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Name of Medication COZAAR

Prophylaxis Yes
No

Indication HIGH BLOOD PRESSURE

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

	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 2005

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes
No

Indication HIGH BLOOD PRESSURE

Dose per administration 12.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Name of Medication HYDROCODONE

Prophylaxis Yes
No

Indication HIP PAIN

Dose per administration 5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

	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 DEC 2019

Start date completely unknown _____ False

Ongoing? _____ Yes

_____ No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? _____ Yes

_____ No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) _____ 802

_____ 803

_____ 804

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Name of Medication MIRTAZAPINE

Prophylaxis Yes
No

Indication DEPRESSION

Dose per administration 15

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

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 NOV 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Name of Medication FLOMAX

Prophylaxis Yes
No

Indication BENIGN PROSTATIC
HYPERPLASIA

Dose per administration 0.4

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Intraocular	<input type="checkbox"/>
Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN NOV 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3512042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 07:59:50

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3512042

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Date of dosing discontinuation (dd MMM yyyy) 01 SEP 2020

Primary reason for dosing discontinuation

AE (specify)

SAE (specify)

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by participant (specify)

Due to SARS-COV-2

Other

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

US3512042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

Date of study discontinuation/completion (*dd MMM yyyy*) 1 SEP 2020

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*) 1 SEP 2020

Was autopsy performed?

Yes

No

Unknown

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

SAEID	USA-US065-2020-MRNA-1273-P30 1000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

SAEID	USA-US065-2020-MRNA-1273-P30 1000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/SEP/2020 14:18
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.	<input checked="" type="checkbox"/> True

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

SAEID	USA-US065-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/SEP/2020 19:51
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.	<input checked="" type="checkbox"/> True

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Feb 2021 20:32:21

Generated On: 10 Jun 2021 07:59:50

SAEID	USA-US065-2020-MRNA-1273-P30 1000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	MICHAEL
Investigator's Last Name	KOREN
Site Address: Street	_____
Site Address: City	_____
Site Address: State	_____
Site Address: Postal Code	_____
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/SEP/2020 17:17
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

Audit

US3512042 (Prod: Jacksonville Center for Clinical Research Center)

US3512042

Form: Participant Creation

Generated On: 10 Jun 2021 07:59:50

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
User entered 'US3512042'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 16:34:40

US3512042

Form: Participant Creation

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57

US3512042

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:59:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:06
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:38:51

US3512042

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:06
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 16:34:41

US3512042

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:59:50

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:06
User entered 'Clinic (Clinic)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:38:51

US3512042

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:59:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'SCRN'	System	12 Aug 2020 17:38:51

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered (b) (6) 1942'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 16:34:42

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '78'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'YEARS'	System	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '78'	System	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered 'Male (M)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '1'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered empty.	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:50

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:58
User entered '0'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:39:41

US3512042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:50

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered '12 Aug 2020'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Aug 2020'	System	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2020'	System	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:50

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered 'Amendment 2 (2)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:50

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered empty.	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:50

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered empty.	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered 'No (N)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:01

US3512042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:41:13
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 16:34:41

US3512042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:50

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	12 Aug 2020 17:40:07

US3512042

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:42:53
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:40:07

US3512042

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:59:50

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:00
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:56:51

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Immune system disorders, HLG: 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) (b) (4)	12 Aug 2020 21:58:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 21:58:22
Data point term sent to Coder	System	12 Aug 2020 21:57:21
User entered 'allergy to sulfa'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2005'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2005'	System	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2005'	System	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 21:57:06

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Immune system disorders, HLG: 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)	12 Aug 2020 21:59:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 21:59:12
Data point term sent to Coder	System	12 Aug 2020 21:58:22
User entered 'allergy to penicillin'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2005'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2005'	System	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2005'	System	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 21:57:36

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:00:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:00:20
Data point term sent to Coder	System	12 Aug 2020 21:59:24
User entered 'environmental allergies'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 11:32:01
User entered 'un UNK 2000' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:32:01
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	12 Aug 2020 21:58:47
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2000'	System	13 Aug 2020 11:32:01
User entered empty.	System	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2000'	System	13 Aug 2020 11:32:01
User entered empty.	System	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 21:58:47

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:00:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:00:20
Data point term sent to Coder	System	12 Aug 2020 21:59:24
User entered 'seasonal allergies'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 1947'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 1947'	System	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1947'	System	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 21:59:10

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:01:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:01:23
Data point term sent to Coder	System	12 Aug 2020 22:00:25
User entered 'gastroesophageal reflux disease'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 1998'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 1998'	System	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1998'	System	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 21:59:35

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:02:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:02:24
Data point term sent to Coder	System	12 Aug 2020 22:01:26
User entered 'heartburn'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 1998'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 1998'	System	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1998'	System	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:00:29

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric ulcer, LLT: Gastric ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:19:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:19:24
Data point term sent to Coder	System	13 Aug 2020 11:32:40
Coding entries removed.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:32:33
User entered 'gastric ULCER gastric' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:32:33
User coded data point as SOC: General disorders and administration site conditions, HLG: Tissue disorders NEC, HLT: Ulcers NEC, PT: Ulcer, LLT: Ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:03:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:03:09
Data point term sent to Coder	System	12 Aug 2020 22:02:27
User entered 'Ulcer'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 1998'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 1998'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 1998'	System	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1998'	System	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 1998'	System	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1998'	System	12 Aug 2020 22:01:44

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:05:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:05:10
Data point term sent to Coder	System	12 Aug 2020 22:04:28
User entered 'constipation'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2019'	System	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:03:36

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:05:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:05:10
Data point term sent to Coder	System	12 Aug 2020 22:04:28
User entered 'enlarged prostate'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un Nov 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Nov 2019'	System	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:04:15

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:06:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:06:10
Data point term sent to Coder	System	12 Aug 2020 22:05:29
User entered 'erectile dysfunction'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2010'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2010'	System	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2010'	System	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:04:58

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:59:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Per DM CLR: Please update the condition to include the laterality of CATARACTS (e.g. Left, Right or Bilateral). 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)	22 Oct 2020 08:14:22
User coded data point as SOC: Eye disorders, HLGT: Coder Import (b) (4) Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\23.0.	(b) (4)	20 Oct 2020 20:54:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	20 Oct 2020 20:54:45
Query 'Per DM CLR: Please update the condition to include the laterality of CATARACTS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:53:39
Coding entries removed.	(b) (4), (b) (6)	20 Oct 2020 20:53:32
User entered 'BILATERAL CATARACTS' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:53:26
User opened query 'Per DM CLR: Please update the condition to include the laterality of CATARACTS (e.g. Left, Right or Bilateral). 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)	23 Sep 2020 12:17:21

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Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 22:07:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	12 Aug 2020 22:07:26
User entered 'cataracts'	System	12 Aug 2020 22:06:30
	Brenda Anderson (b) (4)	12 Aug 2020 22:05:50
	(b) (4)	

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2000'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2010'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2000'	System	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2000'	System	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2010'	System	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2010'	System	12 Aug 2020 22:05:50

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Surgical and medical procedures, HLG: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Intraocular lens implant, LLT: Lens implant - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:21:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:21:22
Data point term sent to Coder	System	12 Aug 2020 22:09:35
User entered 'bilateral lens implant'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2010'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2010'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2010'	System	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2010'	System	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2010'	System	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2010'	System	12 Aug 2020 22:08:45

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Per DM CLR: Please update the condition to include the laterality of HEARING LOSS (e.g. Left, Right or Bilateral). 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)	22 Oct 2020 07:54:05
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:56:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:56:38
Data point term sent to Coder	System	20 Oct 2020 20:54:41
Query 'Per DM CLR: Please update the condition to include the laterality of HEARING LOSS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'BILATERAL' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:54:03
Coding entries removed.	(b) (4), (b) (6)	20 Oct 2020 20:53:58
User entered 'BILATERAL HEARING LOSS' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:53:58
User opened query 'Per DM CLR: Please update the condition to include the laterality of HEARING LOSS (e.g. Left, Right or Bilateral). 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)	23 Sep 2020 12:17:38
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness, LLT: Hearing loss - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:10:13

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	12 Aug 2020 22:10:13 12 Aug 2020 22:09:34
User entered 'hearing loss'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2010'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2010'	System	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2010'	System	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:09:14

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:59:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:32:23
User coded data point as SOC: Eye disorders, HLT: Retina, choroid and vitreous haemorrhages and vascular disorders, HLT: Retinal bleeding and vascular disorders (excl retinopathy), PT: Retinal vascular thrombosis, LLT: Retinal vascular thrombosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 11:23:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 11:23:01
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Per DM CLR: Please update the condition to include the laterality of OCULAR THROMBOSIS (e.g. Left, Right or Bilateral). 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)	22 Oct 2020 08:06:22
Query 'Per DM CLR: Please update the condition to include the laterality of OCULAR THROMBOSIS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'PREDOMINATELY LEFT SIDED' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:54:51
Data point term sent to Coder	System	20 Oct 2020 20:54:41
User entered 'LEFT SIDE OCULAR THROMBOSIS' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:54:39
User opened query 'Per DM CLR: Please update the condition to include the laterality of OCULAR THROMBOSIS (e.g. Left, Right or Bilateral). 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)	23 Sep 2020 12:17:51
Data point term sent to Coder	System	12 Aug 2020 22:10:37

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
User entered 'ocular thrombosis'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '27 Jun 2016'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '27 Jun 2016'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jun 2016'	System	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2016'	System	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jun 2016'	System	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2016'	System	12 Aug 2020 22:10:36

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Nervous system disorders, HLG: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:12:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:12:14
Data point term sent to Coder	System	12 Aug 2020 22:11:43
User entered 'stroke'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '27 Jun 2016'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '27 Jun 2016'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jun 2016'	System	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2016'	System	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jun 2016'	System	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2016'	System	12 Aug 2020 22:11:23

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Nervous system disorders, HLG: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Tremor, LLT: Tremor of hands - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:43:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:43:22
Data point term sent to Coder	System	12 Aug 2020 22:12:46
User entered 'right hand tremor'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 1990'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 1990'	System	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1990'	System	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:12:11

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:14:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:14:16
Data point term sent to Coder	System	12 Aug 2020 22:13:48
User entered 'sleep apnea'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2012'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 11:34:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 11:34:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:34:41
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 22:13:21
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2012'	System	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2012'	System	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:13:21

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Hip fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:28:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:28:21
Data point term sent to Coder	System	12 Aug 2020 22:14:51
User entered 'fracture left hip'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2019'	System	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2019'	System	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	12 Aug 2020 22:14:02

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:59:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:16:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:16:15
Data point term sent to Coder	System	12 Aug 2020 22:14:52
User entered 'high cholesterol'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2005'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 22:14:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 22:14:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:29
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 22:14:23
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2005'	System	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2005'	System	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:14:23

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:59:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:18:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:18:17
Data point term sent to Coder	System	12 Aug 2020 22:16:55
User entered 'high blood pressure'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 11:36:36
User entered 'un UNK 2005' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:36:36
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	12 Aug 2020 22:15:56
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2005'	System	13 Aug 2020 11:36:36
User entered empty.	System	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2005'	System	13 Aug 2020 11:36:36
User entered empty.	System	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:59:50

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:15:56

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:59:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:05:21
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'NO MED REPORTED' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:55:31
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:18:19
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)	12 Aug 2020 22:18:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:18:16
Data point term sent to Coder System	System	12 Aug 2020 22:16:56
User entered 'paroxysmal atrial fibrillation'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2015'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 22:16:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Aug 2020 22:16:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:16:56
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 22:16:52
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2015'	System	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2015'	System	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:16:52

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:20:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:20:16
Data point term sent to Coder	System	12 Aug 2020 22:18:58
User entered 'anxiety'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2019'	System	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:18:44

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:21:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:21:16
Data point term sent to Coder	System	12 Aug 2020 22:20:00
User entered 'depression'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2019'	System	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:19:05

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:22:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:22:17
Data point term sent to Coder	System	12 Aug 2020 22:21:01
User entered 'insomnia'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	13 Aug 2020 11:41:28
User entered 'un UNK 2019' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:41:28
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	12 Aug 2020 22:20:59
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2019'	System	13 Aug 2020 11:41:28
User entered empty.	System	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	13 Aug 2020 11:41:28
User entered empty.	System	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:59:50

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:20:59

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Acetabulum fracture, LLT: Acetabulum fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 00:39:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 00:39:16
Data point term sent to Coder	System	12 Aug 2020 22:22:02
User entered 'acetabular fracture'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'UN Nov 2019' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:25:32
User entered 'un UNK 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'UN Dec 2019' reason for change: Data Entry Error	Brenda Anderson (b) (4)	12 Aug 2020 22:25:32
User entered 'un UNK 2019'	(b) (4) Brenda Anderson (b) (4)	12 Aug 2020 22:21:50
	(b) (4)	

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Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Nov 2019'	System	12 Aug 2020 22:25:32
User entered 'Jan 2019'	System	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Dec 2019'	System	12 Aug 2020 22:25:32
User entered 'Jan 2019'	System	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	12 Aug 2020 22:21:50

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip surgery, LLT: Acetabular surgery - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:28:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:28:16
Data point term sent to Coder	System	12 Aug 2020 22:27:13
User entered 'acetabular surgery'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un Nov 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:06:00
Query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' answered with 'PATIENT HAD TWO SURGERIES, WILL ADD SECOND ON SEPERATE LOG LINE' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:56:39
User entered 'UN Nov 2019' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:56:19
User opened query 'Per DM CLR: Please review the status of this MH as the duration is unexpected for this procedure. Note, procedures/surgeries typically have the same start/stop date. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:18:56
User entered 'un Dec 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Nov 2019'	System	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Nov 2019'	System	20 Oct 2020 20:56:19
User entered 'Dec 2019'	System	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	12 Aug 2020 22:27:10

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spinal stenosis, LLT: Spinal stenosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:29:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:29:20
Data point term sent to Coder	System	12 Aug 2020 22:28:16
User entered 'spinal stenosis'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2013'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2013'	System	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2013'	System	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:27:57

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:59:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
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)	22 Oct 2020 08:11:20
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 'UPDATED' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:57:34
User coded data point as SOC: Surgical and medical procedures, HLG: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Pelvic operation, LLT: Pelvic operation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 08:33:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 08:33:51
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)	23 Sep 2020 12:19:32
Data point term sent to Coder	System	12 Aug 2020 22:29:19
User entered 'pelvic repair surgery'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '08 Aug 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:29:08

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Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	12 Aug 2020 22:30:14
User entered '08 Aug 2019' reason for change: Data Entry Error	Brenda Anderson (b) (4)	12 Aug 2020 22:30:14
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	
User entered 'un UNK 2019'	System	12 Aug 2020 22:29:08
	Brenda Anderson (b) (4)	12 Aug 2020 22:29:08
	(b) (4)	

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Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:29:08

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Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Aug 2019'	System	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Aug 2019'	System	12 Aug 2020 22:30:14
User entered 'Jan 2019'	System	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	12 Aug 2020 22:29:08

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Hepatobiliary disorders, HLG: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis chronic, LLT: Chronic cholecystitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:35:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 11:35:19
Data point term sent to Coder	System	13 Aug 2020 11:34:40
User entered 'chronic cholecystitis'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:33:46

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Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2019'	System	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	13 Aug 2020 11:33:46

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:59:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. 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)	22 Oct 2020 08:04:46
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:03:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:03:31
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'EXACT LOCATIONS UNKNOWN' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 20:59:57
Data point term sent to Coder	System	20 Oct 2020 20:59:51
User entered 'GENERALIZED UNSPECIFIED JOINT OSTEOARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:59:45
Coding entries removed.	(b) (4), (b) (6)	20 Oct 2020 20:59:23
User entered 'GENERALIZED MULTIPLE JOINT OSTEOARTHRITIS' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 20:59:23
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. 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)	23 Sep 2020 12:19:52

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:59:50

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 11:37:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 11:37:29
Data point term sent to Coder	System	13 Aug 2020 11:36:41
User entered 'osteoarthritis'	Brenda Anderson (b) (4)	13 Aug 2020 11:36:10
	(b) (4)	

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Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'un UNK 2019'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered empty.	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	Brenda Anderson (b) (4) (b) (4)	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Jan 2019'	System	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	13 Aug 2020 11:36:10

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Pelvic fractures and dislocations, PT: Pelvic fracture, LLT: Fracture of pelvis - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 09:52:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 09:52:16
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:43:40
Data point term sent to Coder	System	20 Oct 2020 20:58:48
User entered 'BROKEN PELVIS SECONDARY TO FALL'	(b) (4), (b) (6)	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '02 Aug 2019'	(b) (4), (b) (6)	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '08 Aug 2019'	(b) (4), (b) (6)	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Aug 2019'	System	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Aug 2019'	System	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	20 Oct 2020 20:58:07

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:59:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip surgery, LLT: Acetabular surgery - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:59:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 20:59:44
Data point term sent to Coder	System	20 Oct 2020 20:58:50
User entered 'ACETABULAR SURGERY'	(b) (4), (b) (6)	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'UN Dec 2019'	(b) (4), (b) (6)	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:59:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered 'UN Dec 2019'	(b) (4), (b) (6)	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:59:50

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:43:40
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:59:50

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Dec 2019'	System	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:59:50

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'Dec 2019'	System	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '2019'	System	20 Oct 2020 20:58:47

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered '12 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered '12:20'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '12 Aug 2020 12:20'	System	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered '75.0' in	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52
DataPoint set to visible.	(b) (4) System	12 Aug 2020 17:40:07

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered '177.0' lb	Brenda Anderson (b) (4)	12 Aug 2020 22:35:52
DataPoint set to visible.	(b) (4) System	12 Aug 2020 17:40:07

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
Amendment Manager: User entered '22.16974'	System	16 Sep 2020 23:53:43
User entered '22.2'	System	12 Aug 2020 22:35:52
DataPoint set to visible.	System	12 Aug 2020 17:40:07

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'kg/m2'	System	12 Aug 2020 22:35:52
DataPoint set to visible.	System	12 Aug 2020 17:40:07

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:36
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 16:48:38
Query 'Data is required. Please provide.' answered with 'not done' (Site from System).	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:35:58
User opened query 'Data is required. Please provide.' (Site from System).	System	12 Aug 2020 22:35:52
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'bpm'	System	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'breaths/min'	System	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'mmHg'	System	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:36
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'mmHg'	System	12 Aug 2020 22:35:52

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57

US3512042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:50

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57

US3512042

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:49
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:36:10

US3512042

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:51:49
User entered '12 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:36:10

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:50

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:50

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

US3512042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:50

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Screening

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[Manufacturing & Production Operations](#) with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Screening

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Screening

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Screening

Form: Risk of Exposure

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[Educators and Students](#) (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered 'No (N)'	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:36:02
User entered 'No (N)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	12 Aug 2020 22:42:37
Query 'Data is required. Please complete.' answered with 'done' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Brenda Anderson (b) (4)	12 Aug 2020 22:38:18
User entered empty.	System	12 Aug 2020 22:37:57
	Brenda Anderson (b) (4)	12 Aug 2020 22:37:57
	(b) (4)	

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Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:32:23
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:50

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Screening

Form: Risk of Exposure

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[Resides in Multi-family dwelling](#) (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:50

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:50

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered '1'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:32:23
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:31
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:37:57

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:59:50

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:42
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:20:44

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:42
User entered '12 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:20:44

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:59:50

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:52:42
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:20:44

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:59:50

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'VISIT1'	System	28 Aug 2020 19:20:44

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 16:44:38

US3512042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:50

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:54:25
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:54:10
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:54:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 16:44:38
User entered '185331' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 16:44:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:50

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	12 Aug 2020 16:44:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:50

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)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered 'No (N)'	Brenda Anderson (b) (4)	28 Aug 2020 19:20:56
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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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)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:20:56

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Folder: Visit 1 Day 1

Form: Randomization

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Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:20:56

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Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:20:56

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:50

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:54:25
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:20:56

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:50

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4)	
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'Completed' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 06:55:56
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'Completed' (Site from DM).	Allison Crain (b) (4)	04 Nov 2020 16:33:09
User entered 'No (N)'	(b) (4)	
User entered 'No (N)'	Allison Crain (b) (4)	04 Nov 2020 16:33:04
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:48:56
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:18:43
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:47:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '12 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '12:20'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '12 Aug 2020 12:20'	System	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '98.1' F	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered 'Oral (Oral)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered empty.	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '54'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'bpm'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '12'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'breaths/min'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '142'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'mmHg'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:27:27
User closed query 'Per source Diastolic Blood Pressure is 92 and not 82. Please review and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 15:27:23
Query 'Per source Diastolic Blood Pressure is 92 and not 82. Please review and update accordingly. ' answered with 'corrected' (Site from CRA).	Brenda Anderson (b) (4) (b) (4)	06 Nov 2020 18:58:02
User entered '92' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	06 Nov 2020 18:57:50
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:20
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:56:17
User opened query 'Per source Diastolic Blood Pressure is 92 and not 82. Please review and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 12:55:53
User entered '82'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'mmHg'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:50

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered missing code ND - Not Done.	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '12 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '13:58'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '12 Aug 2020 13:58'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 06:23:47
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs per sub investigator' (Site from System).	Brenda Anderson (b) (4) (b) (4)	21 Sep 2020 19:37:51
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:53:43
User entered '96.7' F	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered 'Oral (Oral)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered empty.	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '53'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'bpm'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '12'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'breaths/min'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User entered '150'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'mmHg'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:56:17
User closed query 'Per CDM: Please confirm the value for Diastolic BP.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 05:19:49
Query 'Per CDM: Please confirm the value for Diastolic BP.' answered with 'changed per source' (Site from DM).	Brenda Anderson (b) (4)	10 Sep 2020 18:01:20
User entered '74' reason for change: Data Entry Error	(b) (4)	10 Sep 2020 18:01:09
User opened query 'Per CDM: Please confirm the value for Diastolic BP.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 13:05:41
User entered '14'	Brenda Anderson (b) (4)	28 Aug 2020 19:22:39
	(b) (4)	

US3512042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'mmHg'	System	28 Aug 2020 19:22:39

US3512042

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:50

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:57:24
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:46

US3512042

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:57:24
User entered empty.	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:22:46

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:50

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered empty.	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered empty.	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:50

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:50

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered '12 Aug 2020'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:50

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered '13:28'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '12 Aug 2020 13:28'	System	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered 'Left Arm (LEFT ARM)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 12:57:33
User entered 'ONCE'	System	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:50

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 17:41:02

US3512042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:57:50
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:23:01

US3512042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:57:50
User entered '12 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:23:01

US3512042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:50

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:57:50
User entered '12:58'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:23:01

US3512042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '12 Aug 2020 12:58'	System	28 Aug 2020 19:23:01

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:59:50

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:59:08
User entered '12 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Anderson (b) (4)	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:59:08
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:59:08
User entered '12:40'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '12 Aug 2020 12:40'	System	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:50

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:59:08
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:50

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:59:08
User entered empty.	Brenda Anderson (b) (4) (b) (4)	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:50

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	28 Aug 2020 19:23:17

US3512042

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:59:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:59:17
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	19 Aug 2020 13:24:43

US3512042

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:59:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	19 Aug 2020 13:24:43

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:04:24', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0a04e857-8fc7-4b1a-a63a-53c5e5e39187' User entered 'Yes (Y)'	System	12 Aug 2020 18:05:08
	System	12 Aug 2020 18:05:08

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:04:36', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0a04e857-8fc7-4b1a-a63a-53c5e5e39187' User entered '96.7'	System	12 Aug 2020 18:05:08
	System	12 Aug 2020 18:05:08

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:04:44', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0a04e857-8fc7-4b1a-a63a-53c5e5e39187'	System	12 Aug 2020 18:05:08
User entered 'No (N)'	System	12 Aug 2020 18:05:08

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:05:04', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0a04e857-8fc7-4b1a-a63a-53c5e5e39187' User entered '12 Aug 2020 14:05'	System	12 Aug 2020 18:05:08
	System	12 Aug 2020 18:05:08

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '12 Aug 2020 13:48'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '12 Aug 2020 16:18'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T17:40:12', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '34752f3f-e372-4c2b-a5ee-63cc0794b82d' User entered 'Yes (Y)'	System	12 Aug 2020 21:41:07
	System	12 Aug 2020 21:41:07

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T17:40:21', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '34752f3f-e372-4c2b-a5ee-63cc0794b82d' User entered '97.3'	System	12 Aug 2020 21:41:07
	System	12 Aug 2020 21:41:07

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T17:40:27', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '34752f3f-e372-4c2b-a5ee-63cc0794b82d' User entered 'No (N)'	System	12 Aug 2020 21:41:07
	System	12 Aug 2020 21:41:07

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T17:40:37', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '34752f3f-e372-4c2b-a5ee-63cc0794b82d' User entered '12 Aug 2020 17:40'	System	12 Aug 2020 21:41:07
	System	12 Aug 2020 21:41:07

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '12 Aug 2020 17:13'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 2'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:41:06', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'd597d0f1-b756-4a2f-b945-d52293727951' User entered 'Yes (Y)'	System	13 Aug 2020 20:41:50
	System	13 Aug 2020 20:41:50

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:41:26', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'd597d0f1-b756-4a2f-b945-d52293727951' User entered '98.1'	System	13 Aug 2020 20:41:50
	System	13 Aug 2020 20:41:50

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:41:31', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'd597d0f1-b756-4a2f-b945-d52293727951' User entered 'No (N)'	System	13 Aug 2020 20:41:50
	System	13 Aug 2020 20:41:50

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:41:43', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'd597d0f1-b756-4a2f-b945-d52293727951' User entered '13 Aug 2020 16:41'	System	13 Aug 2020 20:41:50
	System	13 Aug 2020 20:41:50

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 3'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:24:52', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '08b5563e-d5a5-47e5-aef0-34ddde3a5bfa' User entered 'Yes (Y)'	System	14 Aug 2020 16:25:18
	System	14 Aug 2020 16:25:18

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:25:02', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '08b5563e-d5a5-47e5-ae0-34ddde3a5bfa' User entered '97.2'	System	14 Aug 2020 16:25:18
	System	14 Aug 2020 16:25:18

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:25:06', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '08b5563e-d5a5-47e5-aef0-34ddde3a5bfa'	System	14 Aug 2020 16:25:18
User entered 'No (N)'	System	14 Aug 2020 16:25:18

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:25:16', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '08b5563e-d5a5-47e5-aef0-34ddde3a5bfa' User entered '14 Aug 2020 12:25'	System	14 Aug 2020 16:25:18
	System	14 Aug 2020 16:25:18

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 4'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:28:25', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'e3ea7798-6c24-40d2-b7d4-9e134c68d9d0'	System	15 Aug 2020 16:28:53
User entered 'Yes (Y)'	System	15 Aug 2020 16:28:53

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:28:37', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'e3ea7798-6c24-40d2-b7d4-9e134c68d9d0' User entered '96.7'	System	15 Aug 2020 16:28:53
	System	15 Aug 2020 16:28:53

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:28:42', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'e3ea7798-6c24-40d2-b7d4-9e134c68d9d0'	System	15 Aug 2020 16:28:53
User entered 'No (N)'	System	15 Aug 2020 16:28:53

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:28:52', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'e3ea7798-6c24-40d2-b7d4-9e134c68d9d0'	System	15 Aug 2020 16:28:53
User entered '15 Aug 2020 12:28'	System	15 Aug 2020 16:28:53

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 5'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:17', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '39d940c3-000a-4889-a603-483e1050b1e2' User entered 'Yes (Y)'	System	16 Aug 2020 19:16:40
	System	16 Aug 2020 19:16:40

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:23', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '39d940c3-000a-4889-a603-483e1050b1e2' User entered '96.3'	System	16 Aug 2020 19:16:40
	System	16 Aug 2020 19:16:40

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:31', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '39d940c3-000a-4889-a603-483e1050b1e2'	System	16 Aug 2020 19:16:40
User entered 'No (N)'	System	16 Aug 2020 19:16:40

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:37', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '39d940c3-000a-4889-a603-483e1050b1e2' User entered '16 Aug 2020 15:16'	System	16 Aug 2020 19:16:40
	System	16 Aug 2020 19:16:40

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 6'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:13:19', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'a762c0a9-1877-4ac5-b548-cbdb0b94cbc0' User entered 'Yes (Y)'	System	17 Aug 2020 21:13:39
	System	17 Aug 2020 21:13:39

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:13:26', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'a762c0a9-1877-4ac5-b548-cbdb0b94cbc0' User entered '97.4'	System	17 Aug 2020 21:13:39
	System	17 Aug 2020 21:13:39

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:13:31', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'a762c0a9-1877-4ac5-b548-cbdb0b94cbc0' User entered 'No (N)'	System	17 Aug 2020 21:13:39
	System	17 Aug 2020 21:13:39

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:13:38', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'a762c0a9-1877-4ac5-b548-cbdb0b94cbc0' User entered '17 Aug 2020 17:13'	System	17 Aug 2020 21:13:39
	System	17 Aug 2020 21:13:39

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 7'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:05', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7f6d4c82-d367-4683-9b46-a8a05b6e026e' User entered 'Yes (Y)'	System	18 Aug 2020 18:30:36
	System	18 Aug 2020 18:30:36

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:15', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7f6d4c82-d367-4683-9b46-a8a05b6e026e' User entered '97.2'	System	18 Aug 2020 18:30:36
	System	18 Aug 2020 18:30:36

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:28', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7f6d4c82-d367-4683-9b46-a8a05b6e026e' User entered 'No (N)'	System	18 Aug 2020 18:30:36
	System	18 Aug 2020 18:30:36

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:35', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7f6d4c82-d367-4683-9b46-a8a05b6e026e' User entered '18 Aug 2020 14:30'	System	18 Aug 2020 18:30:36
	System	18 Aug 2020 18:30:36

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:06:08', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '9556a203-0fd7-4fc9-ac2d-5e028baf06b0'	System	12 Aug 2020 18:07:02
User entered 'None (1)'	System	12 Aug 2020 18:07:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:06:24', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '9556a203-0fd7-4fc9-ac2d-5e028baf06b0'	System	12 Aug 2020 18:07:02
User entered 'No (N)'	System	12 Aug 2020 18:07:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:06:32', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '9556a203-0fd7-4fc9-ac2d-5e028baf06b0'	System	12 Aug 2020 18:07:02
User entered 'No (N)'	System	12 Aug 2020 18:07:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:06:42', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '9556a203-0fd7-4fc9-ac2d-5e028baf06b0'	System	12 Aug 2020 18:07:02
User entered 'None (1)'	System	12 Aug 2020 18:07:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T14:07:00', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '9556a203-0fd7-4fc9-ac2d-5e028baf06b0' User entered '12 Aug 2020 14:07'	System	12 Aug 2020 18:07:02
	System	12 Aug 2020 18:07:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '12 Aug 2020 13:48'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '12 Aug 2020 16:18'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:51:44', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '2a64bdcc-fe34-476b-a3f2-bb591631de3e'	System	13 Aug 2020 15:52:30
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 15:52:30

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:51:49', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '2a64bdcc-fe34-476b-a3f2-bb591631de3e' User entered 'No (N)'	System	13 Aug 2020 15:52:30
	System	13 Aug 2020 15:52:30

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:51:57', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '2a64bdcc-fe34-476b-a3f2-bb591631de3e' User entered 'No (N)'	System	13 Aug 2020 15:52:30
	System	13 Aug 2020 15:52:30

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:52:05', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '2a64bdcc-fe34-476b-a3f2-bb591631de3e'	System	13 Aug 2020 15:52:30
User entered 'None (1)'	System	13 Aug 2020 15:52:30

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:52:28', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '2a64bdcc-fe34-476b-a3f2-bb591631de3e' User entered '13 Aug 2020 11:52'	System	13 Aug 2020 15:52:30
	System	13 Aug 2020 15:52:30

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '12 Aug 2020 17:13'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 2'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:41:59', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '1c320f62-88b3-406f-9b6d-16a8c3d4c6ba'	System	13 Aug 2020 20:42:43
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 20:42:43

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:42:11', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '1c320f62-88b3-406f-9b6d-16a8c3d4c6ba' User entered 'No (N)'	System	13 Aug 2020 20:42:43
	System	13 Aug 2020 20:42:43

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:42:21', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '1c320f62-88b3-406f-9b6d-16a8c3d4c6ba' User entered 'No (N)'	System	13 Aug 2020 20:42:43
	System	13 Aug 2020 20:42:43

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:42:31', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '1c320f62-88b3-406f-9b6d-16a8c3d4c6ba' User entered 'None (1)'	System	13 Aug 2020 20:42:43
	System	13 Aug 2020 20:42:43

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:42:41', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '1c320f62-88b3-406f-9b6d-16a8c3d4c6ba' User entered '13 Aug 2020 16:42'	System	13 Aug 2020 20:42:43
	System	13 Aug 2020 20:42:43

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 3'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:05', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'b3dc2f52-47c9-4a5b-bb15-751bfa666edd' User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 16:26:37
	System	14 Aug 2020 16:26:37

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:14', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'b3dc2f52-47c9-4a5b-bb15-751bfa666edd' User entered 'No (N)'	System	14 Aug 2020 16:26:37
	System	14 Aug 2020 16:26:37

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:19', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'b3dc2f52-47c9-4a5b-bb15-751bfa666edd' User entered 'No (N)'	System	14 Aug 2020 16:26:37
	System	14 Aug 2020 16:26:37

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:25', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'b3dc2f52-47c9-4a5b-bb15-751bfa666edd' User entered 'None (1)'	System	14 Aug 2020 16:26:37
	System	14 Aug 2020 16:26:37

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:36', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'b3dc2f52-47c9-4a5b-bb15-751bfa666edd' User entered '14 Aug 2020 12:26'	System	14 Aug 2020 16:26:37
	System	14 Aug 2020 16:26:37

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 4'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:00', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7d1c6e66-172f-481a-bcf3-134aa658f8a0'	System	15 Aug 2020 16:29:40
User entered 'None (1)'	System	15 Aug 2020 16:29:40

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:11', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7d1c6e66-172f-481a-bcf3-134aa658f8a0' User entered 'No (N)'	System	15 Aug 2020 16:29:40
	System	15 Aug 2020 16:29:40

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:19', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7d1c6e66-172f-481a-bcf3-134aa658f8a0' User entered 'No (N)'	System	15 Aug 2020 16:29:40
	System	15 Aug 2020 16:29:40

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:26', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7d1c6e66-172f-481a-bcf3-134aa658f8a0'	System	15 Aug 2020 16:29:40
User entered 'None (1)'	System	15 Aug 2020 16:29:40

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:36', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7d1c6e66-172f-481a-bcf3-134aa658f8a0' User entered '15 Aug 2020 12:29'	System	15 Aug 2020 16:29:40
	System	15 Aug 2020 16:29:40

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 5'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:44', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ec513025-9f63-4f7c-aab3-ac8065788636'	System	16 Aug 2020 19:17:24
User entered 'None (1)'	System	16 Aug 2020 19:17:24

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:49', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ec513025-9f63-4f7c-aab3-ac8065788636'	System	16 Aug 2020 19:17:24
User entered 'No (N)'	System	16 Aug 2020 19:17:24

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:16:58', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ec513025-9f63-4f7c-aab3-ac8065788636' User entered 'No (N)'	System	16 Aug 2020 19:17:24
	System	16 Aug 2020 19:17:24

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:04', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ec513025-9f63-4f7c-aab3-ac8065788636'	System	16 Aug 2020 19:17:24
User entered 'None (1)'	System	16 Aug 2020 19:17:24

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:21', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ec513025-9f63-4f7c-aab3-ac8065788636' User entered '16 Aug 2020 15:17'	System	16 Aug 2020 19:17:24
	System	16 Aug 2020 19:17:24

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 6'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:13:47', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'fa2eefe0-c424-4d4b-acf3-8e16a4b813d9'	System	17 Aug 2020 21:14:23
User entered 'None (1)'	System	17 Aug 2020 21:14:23

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:13:56', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'fa2eefe0-c424-4d4b-acf3-8e16a4b813d9' User entered 'No (N)'	System	17 Aug 2020 21:14:23
	System	17 Aug 2020 21:14:23

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:02', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'fa2eefe0-c424-4d4b-acf3-8e16a4b813d9'	System	17 Aug 2020 21:14:23
User entered 'No (N)'	System	17 Aug 2020 21:14:23

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:08', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'fa2eefe0-c424-4d4b-acf3-8e16a4b813d9'	System	17 Aug 2020 21:14:23
User entered 'None (1)'	System	17 Aug 2020 21:14:23

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:21', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'fa2eefe0-c424-4d4b-acf3-8e16a4b813d9' User entered '17 Aug 2020 17:14'	System	17 Aug 2020 21:14:23
	System	17 Aug 2020 21:14:23

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 7'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:44', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ad84e101-a690-4168-9a24-0e18d77e4140' User entered 'None (1)'	System	18 Aug 2020 18:31:09
	System	18 Aug 2020 18:31:09

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:49', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ad84e101-a690-4168-9a24-0e18d77e4140' User entered 'No (N)'	System	18 Aug 2020 18:31:09
	System	18 Aug 2020 18:31:09

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:30:53', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ad84e101-a690-4168-9a24-0e18d77e4140' User entered 'No (N)'	System	18 Aug 2020 18:31:09
	System	18 Aug 2020 18:31:09

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:00', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ad84e101-a690-4168-9a24-0e18d77e4140' User entered 'None (1)'	System	18 Aug 2020 18:31:09
	System	18 Aug 2020 18:31:09

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:06', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: 'ad84e101-a690-4168-9a24-0e18d77e4140' User entered '18 Aug 2020 14:31'	System	18 Aug 2020 18:31:09
	System	18 Aug 2020 18:31:09

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:29:49', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc' User entered 'None (0)'	System	12 Aug 2020 19:31:18
	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:30:03', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc' User entered 'No interference with activity (1)'	System	12 Aug 2020 19:31:18
	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:30:07', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc' User entered 'None (0)'	System	12 Aug 2020 19:31:18
	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:30:13', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc' User entered 'None (0)'	System	12 Aug 2020 19:31:18
	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:30:17', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc' User entered 'None (0)'	System	12 Aug 2020 19:31:18
	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:30:27', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc' User entered 'None (0)'	System	12 Aug 2020 19:31:18
	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:30:38', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc' User entered 'No (N)'	System	12 Aug 2020 19:31:18
	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-12T15:31:12', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63cc5eb2-3d57-4656-b461-af3131cb4cbc' User entered '12 Aug 2020 15:31'	System	12 Aug 2020 19:31:18
	System	12 Aug 2020 19:31:18

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '12 Aug 2020 13:48'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '12 Aug 2020 16:18'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:52:49', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad'	System	13 Aug 2020 15:54:05
User entered 'No interference with activity (1)'	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:53:03', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad'	System	13 Aug 2020 15:54:05
User entered 'Some interference with activity (2)'	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:53:22', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad' User entered 'None (0)'	System	13 Aug 2020 15:54:05
	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:53:30', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad' User entered 'None (0)'	System	13 Aug 2020 15:54:05
	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:53:34', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad' User entered 'None (0)'	System	13 Aug 2020 15:54:05
	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:53:38', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad'	System	13 Aug 2020 15:54:05
User entered 'None (0)'	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:53:48', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad'	System	13 Aug 2020 15:54:05
User entered 'No (N)'	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T11:54:01', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '7e84f662-7396-48da-8f20-516f6e245bad' User entered '13 Aug 2020 11:54'	System	13 Aug 2020 15:54:05
	System	13 Aug 2020 15:54:05

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '12 Aug 2020 17:13'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 2'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:01', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3' User entered 'None (0)'	System	13 Aug 2020 20:43:58
	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:09', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3'	System	13 Aug 2020 20:43:58
User entered 'No interference with activity (1)'	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:15', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3' User entered 'None (0)'	System	13 Aug 2020 20:43:58
	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:22', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3' User entered 'None (0)'	System	13 Aug 2020 20:43:58
	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:30', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3' User entered 'None (0)'	System	13 Aug 2020 20:43:58
	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:35', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3' User entered 'None (0)'	System	13 Aug 2020 20:43:58
	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:42', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3' User entered 'No (N)'	System	13 Aug 2020 20:43:58
	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-13T16:43:55', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '4d237cb6-69d3-4590-b423-65f45140e9f3'	System	13 Aug 2020 20:43:58
User entered '13 Aug 2020 16:43'	System	13 Aug 2020 20:43:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 3'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:45', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6' User entered 'None (0)'	System	14 Aug 2020 16:27:31
	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:52', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6' User entered 'No interference with activity (1)'	System	14 Aug 2020 16:27:31
	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:26:57', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6' User entered 'None (0)'	System	14 Aug 2020 16:27:31
	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:27:03', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6' User entered 'None (0)'	System	14 Aug 2020 16:27:31
	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:27:07', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6' User entered 'None (0)'	System	14 Aug 2020 16:27:31
	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:27:11', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6' User entered 'None (0)'	System	14 Aug 2020 16:27:31
	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:27:19', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6' User entered 'No (N)'	System	14 Aug 2020 16:27:31
	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-14T12:27:29', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '029b4939-74c6-4f08-b1b9-cc588b7c81c6' User entered '14 Aug 2020 12:27'	System	14 Aug 2020 16:27:31
	System	14 Aug 2020 16:27:31

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 4'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:44', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619' User entered 'None (0)'	System	15 Aug 2020 16:30:32
	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:51', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619' User entered 'No interference with activity (1)'	System	15 Aug 2020 16:30:32
	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:55', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619' User entered 'None (0)'	System	15 Aug 2020 16:30:32
	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:29:59', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619' User entered 'None (0)'	System	15 Aug 2020 16:30:32
	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:30:03', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619' User entered 'None (0)'	System	15 Aug 2020 16:30:32
	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:30:09', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619' User entered 'None (0)'	System	15 Aug 2020 16:30:32
	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:30:15', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619' User entered 'No (N)'	System	15 Aug 2020 16:30:32
	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-15T12:30:27', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '63e6754f-6bd1-4c88-84ce-0c180c38e619' User entered '15 Aug 2020 12:30'	System	15 Aug 2020 16:30:32
	System	15 Aug 2020 16:30:32

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 5'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:27', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78' User entered 'None (0)'	System	16 Aug 2020 19:17:58
	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:33', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78' User entered 'None (0)'	System	16 Aug 2020 19:17:58
	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:36', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78' User entered 'None (0)'	System	16 Aug 2020 19:17:58
	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:39', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78' User entered 'None (0)'	System	16 Aug 2020 19:17:58
	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:42', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78' User entered 'None (0)'	System	16 Aug 2020 19:17:58
	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:45', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78' User entered 'None (0)'	System	16 Aug 2020 19:17:58
	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:48', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78' User entered 'No (N)'	System	16 Aug 2020 19:17:58
	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-16T15:17:56', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '3609ef54-767e-4aab-a8a4-df27f312df78'	System	16 Aug 2020 19:17:58
User entered '16 Aug 2020 15:17'	System	16 Aug 2020 19:17:58

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 6'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:29', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88' User entered 'None (0)'	System	17 Aug 2020 21:15:12
	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:34', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88' User entered 'None (0)'	System	17 Aug 2020 21:15:12
	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:39', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88' User entered 'None (0)'	System	17 Aug 2020 21:15:12
	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:41', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88' User entered 'None (0)'	System	17 Aug 2020 21:15:12
	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:45', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88' User entered 'None (0)'	System	17 Aug 2020 21:15:12
	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:49', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88' User entered 'None (0)'	System	17 Aug 2020 21:15:12
	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:14:58', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88'	System	17 Aug 2020 21:15:12
User entered 'No (N)'	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-17T17:15:10', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '0f9113f1-6d06-4a8f-8268-c8eb1a1b2b88' User entered '17 Aug 2020 17:15'	System	17 Aug 2020 21:15:12
	System	17 Aug 2020 21:15:12

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:50

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
Data entry locked.	System	12 Aug 2020 17:41:02
User entered 'Day 7'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:50

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:13', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21' User entered 'None (0)'	System	18 Aug 2020 18:32:00
	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:50

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:16', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21' User entered 'None (0)'	System	18 Aug 2020 18:32:00
	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:50

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:20', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21' User entered 'None (0)'	System	18 Aug 2020 18:32:00
	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:50

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:23', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21' User entered 'None (0)'	System	18 Aug 2020 18:32:00
	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:50

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:27', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21' User entered 'None (0)'	System	18 Aug 2020 18:32:00
	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:50

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:30', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21' User entered 'None (0)'	System	18 Aug 2020 18:32:00
	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:37', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21' User entered 'No (N)'	System	18 Aug 2020 18:32:00
	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9FCE6FCA-B252-4B10-8B6E-1EB0404629EF)', Time: '2020-08-18T14:31:44', User OID: 'PatientReportedOutcome (US3512042)', ODM File OID: '46a5a386-2b60-41a0-a887-dc809bc31f21' User entered '18 Aug 2020 14:31'	System	18 Aug 2020 18:32:00
	System	18 Aug 2020 18:32:00

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:41:02

US3512042

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:31:28
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:41:02

US3512042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:02:52
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	19 Aug 2020 13:25:12

US3512042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:02:52
User entered '19 Aug 2020'	Sheldon Warren (b) (4) (b) (4)	19 Aug 2020 13:25:12

US3512042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:02:52
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	19 Aug 2020 13:25:12

US3512042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:02:52
User entered empty.	Sheldon Warren (b) (4) (b) (4)	19 Aug 2020 13:25:12

US3512042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:04:39
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	19 Aug 2020 13:25:19

US3512042

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'I'	System	19 Aug 2020 13:25:19

US3512042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:06:55
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	26 Aug 2020 13:37:17

US3512042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:06:55
User entered '26 Aug 2020'	Sheldon Warren (b) (4) (b) (4)	26 Aug 2020 13:37:17

US3512042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:50

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:06:55
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	26 Aug 2020 13:37:17

US3512042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:50

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:06:55
User entered empty.	Sheldon Warren (b) (4) (b) (4)	26 Aug 2020 13:37:17

US3512042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:50

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:07:01
User entered 'Yes (Y)'	Sheldon Warren (b) (4) (b) (4)	26 Aug 2020 13:37:25

US3512042

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:50

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered 'I'	System	26 Aug 2020 13:37:25

US3512042

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:59:50

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:19
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 12:31:09

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:17:49
User entered 'USA-US065-2020-mRNA-1273-P301000001'	System	02 Sep 2020 18:17:12
User entered 'New'	(b) (4), (b) (6)	02 Sep 2020 18:17:12

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'PV Query: Please consider updating the event term to the underlying cause of death, if known. If the fatal event is to remain as cardiopulmonary arrest, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:16:32
Query 'PV Query: Please consider updating the event term to the underlying cause of death, if known. If the fatal event is to remain as cardiopulmonary arrest, please state so.' answered with 'Cause of death on death certificate from patient PCP is cardiopulmonary arrest. Patient passed away at home, there are no additional details or diagnosis' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:43:31
User opened query 'PV Query: Please consider updating the event term to the underlying cause of death, if known. If the fatal event is to remain as cardiopulmonary arrest, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:04:10
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Cardio-respiratory arrest, LLT: Cardiopulmonary arrest - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:12:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 14:12:51
Data point term sent to Coder	System	02 Sep 2020 14:08:51
User entered 'cardiopulmonary arrest'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'PV Query: It was reported, the subject was sick on 30 AUG 2020. Please provide the subject's signs/symptoms.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:16:42
Query 'PV Query: It was reported, the subject was sick on 30 AUG 2020. Please provide the subject's signs/symptoms.' answered with 'will update AE page to include symptoms reported by patient family. He had 3 episodes of vomiting in the days leading up to his passing.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:54:00
User opened query 'PV Query: It was reported, the subject was sick on 30 AUG 2020. Please provide the subject's signs/symptoms.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:03:05
User entered '1 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Sep 2020 14:10:32
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 14:10:32
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:10:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 14:10:11
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Sep 2020 14:10:11
User entered 'un:un' (non-conformant).	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:10:11
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	02 Sep 2020 14:10:32
User entered '1 Sep 2020 UN:UN' (non-conformant).	System	02 Sep 2020 14:10:11
User entered empty.	System	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '1 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'PV query: Please update the severity to grade 5 as the subject died.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:16:53
Query 'PV query: Please update the severity to grade 5 as the subject died.' answered with 'grade 5 is not an option on the radio buttons provided?' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:50:55
User opened query 'PV query: Please update the severity to grade 5 as the subject died.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:06:56
User entered 'Grade 4 (Grade 4)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '1'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 20:01:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 20:01:28
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 20:01:28
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 14:08:28
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'None (NONE)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '1'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Fatal (FATAL)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'PV Query: Please provide death certificate to safety_moderna@iqvia.com.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:17:34
User closed query 'PV query: Please confirm if the subject had chest pain, shortness of breath, irregular heartbeats, dizziness, slurred speech, confusion, headaches or changes in blood pressure recently.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:17:29
User closed query 'PV Query: What type of CVA did the subject had in 2016 (hemorrhagic, ischemic)?' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:17:23
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Sep 2020 21:17:20
Query 'PV Query: Please provide death certificate to safety_moderna@iqvia.com.' answered with 'will email' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:50:30
Query 'PV Query: What type of CVA did the subject had in 2016 (hemorrhagic, ischemic)?' answered with '"ocular thrombus stroke" is what patient reported at time of med history collection, "status post CVA" and "stroke" are all that is listed in medical records' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:48:40
Query 'PV query: Please confirm if the subject had chest pain, shortness of breath, irregular heartbeats, dizziness, slurred speech, confusion, headaches or changes in blood pressure recently.' answered with 'unknown, none of those symptoms were reported by family members and none reported in weekly protocol phone calls.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:44:52
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'No known autopsy available' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 19:44:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide death certificate to safety_moderna@iqvia.com.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:10:16
Query 'PV query: Please provide death certificate.' canceled (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:10:04
User opened query 'PV query: Please confirm if the subject had chest pain, shortness of breath, irregular heartbeats, dizziness, slurred speech, confusion, headaches or changes in blood pressure recently.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:07:17
User opened query 'PV query: Please provide death certificate.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:03:48
User opened query 'PV Query: What type of CVA did the subject had in 2016 (hemorrhagic, ischemic)?' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:03:32
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:02:36
User entered 'PT EXPERIENCED FATAL SAE ON 9/1/2020. HE STOPPED ASA 2-5 DAYS PRIOR TO DEATH IN PREPARATION FOR PLANNED COCHLEAR IMPLANT PROCEDURE ON 9/3/2020. PT HAS HISTORY OF A-FIB, HTN AND HYPERLIPIDEMIA. HE WAS NEGATIVE FOR FEVER, WEIGHT CHANGE, SWELLING. HIS WIFE REPORTED HE WAS SICK ON SUNDAY AND HAD THREE EPISODES OF VOMITING ON 8/31/2020' reason for change: Data Entry Error	Brenda Anderson (b) (4)	02 Sep 2020 14:08:55
User entered 'pt experienced fatal SAE on 9/1/2020. He stopped ASA 2-5 days prior to death in preparation for planned cochlear implant procedure on 9/3/2020. Pt has history of a-fib, htn and hyperlipidemia. HE was neegative for fever, weight change, swelling. HIs wife reported he was sick on Sunday and had three episodes of vomiting on 8/31/2020'	Brenda Anderson (b) (4)	02 Sep 2020 14:08:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	02 Sep 2020 14:08:28

US3512042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	02 Sep 2020 14:08:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:50

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 05:49:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 05:49:42
Data point term sent to Coder	System	18 Sep 2020 21:10:07
User entered 'VOMITTING X3' reason for change:	Brenda Anderson (b) (4)	18 Sep 2020 21:09:11
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 20:44:22
User entered 'vomitting x3'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '31 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '31 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 20:44:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:26
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:00
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 20:44:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:26
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:00
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 20:44:26
User entered 'None (NONE)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:26
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:00
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Sep 2020 20:44:59
User entered '1' reason for change: Data Entry Error	Brenda Anderson (b) (4)	18 Sep 2020 20:44:59
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	18 Sep 2020 20:44:00
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 20:44:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:59
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 20:44:00
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '0'	System	18 Sep 2020 20:44:00

US3512042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '0'	System	18 Sep 2020 20:44:00

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:15:46
Query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'pt passed no illness visit completed' (Site from DM).	Brenda Anderson (b) (4)	23 Oct 2020 14:55:27
User opened query 'Per MM, Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:36:33
User coded data point as SOC: General disorders and administration site conditions, HLGTT: General system disorders NEC, HLT: Asthenic conditions, PT: Malaise, LLT: Malaise - version MedDRA\23.0.	Coder Import (b) (4)	18 Sep 2020 21:05:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Sep 2020 21:05:42
Data point term sent to Coder	System	18 Sep 2020 21:04:57
User entered 'malaise'	Brenda Anderson (b) (4)	18 Sep 2020 21:04:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '30 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	18 Sep 2020 21:04:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '01 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:05:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:05:12
User entered 'None (NONE)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:05:12
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:04:50
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '1'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:05:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:05:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:05:12
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:04:50
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '0'	System	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '0'	System	18 Sep 2020 21:04:50

US3512042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:59:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:16:04
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:44
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'pt passed no illness visit completed' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	23 Oct 2020 14:55:39
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:36:46
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:12:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:12:37
Data point term sent to Coder	System	18 Sep 2020 21:11:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Nausea'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '30 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '01 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:10:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:10:27
User entered 'None (NONE)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:27
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:10:17
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '1'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered '0'	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:10:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:10:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Brenda Anderson (b) (4)	18 Sep 2020 21:10:27
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:10:17
User entered empty.	Brenda Anderson (b) (4)	18 Sep 2020 21:10:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:11:22
User entered empty.	Brenda Anderson (b) (4) (b) (4)	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '0'	System	18 Sep 2020 21:10:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '0'	System	18 Sep 2020 21:10:17

US3512042

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:59:50

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:59:50

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:53
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	12 Aug 2020 17:44:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ENTERIC ASPIRIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 00:17:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 00:17:19
Data point term sent to Coder	System	12 Aug 2020 22:49:50
User entered 'enteric aspirin'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	23 Oct 2020 14:56:25
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 05:38:19
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'corrected' (Site from DM).	Brenda Anderson (b) (4)	23 Oct 2020 14:56:32
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:39:01
User entered 'Post stroke'	Brenda Anderson (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '81'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:36:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:28
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:49:18
User entered 'un UNK 2016'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:49:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	12 Aug 2020 22:49:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	12 Aug 2020 22:49:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '804 (804)'	System	12 Aug 2020 22:49:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:52:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:52:15
Data point term sent to Coder	System	12 Aug 2020 22:50:52
User entered 'tylenol'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
Query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS HIP (e.g. left, right, bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:43:37
User opened query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS HIP (e.g. left, right, bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:39:23
User entered 'osteoarthritis hip'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '600'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'as needed (PRN)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:52:03
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:50:48
User entered 'un UNK 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:50:48

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:55:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:55:20
Data point term sent to Coder	System	12 Aug 2020 22:53:58
User entered 'benadryl'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'seasonal allergies'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '25'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'as needed (PRN)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:40
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:53:21
User entered 'un UNK 2000'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:53:21

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:57:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:57:33
Data point term sent to Coder	System	12 Aug 2020 22:57:01
Coding entries removed.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:52
User entered 'lipitor' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:56:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:56:18
Data point term sent to Coder	System	12 Aug 2020 22:54:59
User entered 'atorvastatin'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'high cholesterol'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '20'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Brenda Anderson (b) (4)	12 Aug 2020 22:54:39
answered with 'confirm as is' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:54:32
User entered 'un UNK 2010'	Brenda Anderson (b) (4)	12 Aug 2020 22:54:32
	(b) (4)	

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '804 (804)'	System	12 Aug 2020 22:54:32

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN POTASSIUM, PRODUCTSYNONYM: COZAAR - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:57:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 22:57:20
Data point term sent to Coder	System	12 Aug 2020 22:57:01
User entered 'Cozaar'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'high blood pressure'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '100'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is ' (Site from System).	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:56:25
User entered 'un UNK 2005'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '804 (804)'	System	12 Aug 2020 22:56:25

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:06:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:06:28
Data point term sent to Coder	System	12 Aug 2020 22:59:04
User entered 'hydrochlorothiazide'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'high blood pressure'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '12.5'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:31
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Brenda Anderson (b) (4)	12 Aug 2020 22:59:00
answered with 'confirm as is' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:58:18
User entered 'un UNK 2015'	Brenda Anderson (b) (4)	12 Aug 2020 22:58:18
	(b) (4)	

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '804 (804)'	System	12 Aug 2020 22:58:18

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:03:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 14:03:31
Data point term sent to Coder	System	12 Aug 2020 23:00:08
User entered 'hydrocodone'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:43:50
Query 'Per DM CLR: Please update the indication to reflect the location of HIP PAIN (e.g. left, right, bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:43:48
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:40:58
User opened query 'Per DM CLR: Please update the indication to reflect the location of HIP PAIN (e.g. left, right, bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 10:40:46
User entered 'hip pain'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '5'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'as needed (PRN)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:39
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Brenda Anderson (b) (4)	12 Aug 2020 22:59:57
answered with 'confirm as is' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 22:59:49
User entered 'un Dec 2019'	Brenda Anderson (b) (4)	12 Aug 2020 22:59:49
	(b) (4)	

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered empty.	System	12 Aug 2020 22:59:49

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:52:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:52:53
Data point term sent to Coder	System	02 Sep 2020 12:51:21
Coding entries removed.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 12:50:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 10:43:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 10:43:04
Data point term sent to Coder	System	14 Aug 2020 20:37:52
User closed query '	System	14 Aug 2020 20:37:50
DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' (Site from System). Query '	Taylor Johnson (b) (4) (b) (4)	14 Aug 2020 20:37:50
DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' answered with 'data updated' (Site from System).		
Data point term sent to Coder	System	14 Aug 2020 20:37:50
User entered 'mirtazapine' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	14 Aug 2020 20:37:43
User opened query '	Coder Import (b) (4) (b) (4)	13 Aug 2020 06:57:16

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Name of Medication](#)

Audit	User	Time (GMT)
DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' (Site from System).		
Data point term sent to Coder	System	12 Aug 2020 23:02:14
User entered 'Acudep'	Brenda Anderson (b) (4)	12 Aug 2020 23:02:11
	(b) (4)	

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'depression' reason for change: Data Entry Error	Brenda Anderson (b) (4)	02 Sep 2020 12:50:50
User entered 'benign prostatic hyperplasia'	(b) (4) Brenda Anderson (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '15'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:49
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 23:02:11
User entered 'un Nov 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '804 (804)'	System	12 Aug 2020 23:02:11

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:05:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 23:05:19
Data point term sent to Coder	System	12 Aug 2020 23:04:16
User entered 'Flomax'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'benign prostatic hyperplasia'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0.4'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'mg (mg)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'once daily (QD)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 04:37:57
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm as is' (Site from System).	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 23:04:04
User entered 'un Nov 2019'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered '0'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

US3512042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'Yes (Y)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered empty.	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:28:38
User entered 'No (N)'	Brenda Anderson (b) (4) (b) (4)	12 Aug 2020 23:04:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	12 Aug 2020 23:04:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '1'	System	12 Aug 2020 23:04:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User entered '804 (804)'	System	12 Aug 2020 23:04:04

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:59:50

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
User closed query 'Per CDM: Patient died on 01 Sep 2020. Please consider updating the date to be consistent with the end of discontinuation date.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Sep 2020 11:29:11
Query 'Per CDM: Patient died on 01 Sep 2020. Please consider updating the date to be consistent with the end of discontinuation date.' answered with 'changed per query' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 17:57:37
User entered '01 Sep 2020' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 17:57:28
User opened query 'Per CDM: Patient died on 01 Sep 2020. Please consider updating the date to be consistent with the end of discontinuation date.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 04:33:08
User entered '12 Aug 2020'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:56:39

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:59:50

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
User closed query 'Per CDM: Since participant died. Please consider updating to DEATH. Then remove entry of cardiopulmonary arrest below.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Sep 2020 11:29:30
Query 'Per CDM: Since participant died. Please consider updating to DEATH. Then remove entry of cardiopulmonary arrest below.' answered with 'changed per query' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 17:57:47
User entered 'Death (DEATH)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 17:57:28
User opened query 'Per CDM: Since participant died. Please consider updating to DEATH. Then remove entry of cardiopulmonary arrest below.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 07:25:24
User entered 'SAE (specify) (SAE)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:56:39

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	(b) (4) System	10 Sep 2020 17:57:54
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4)	10 Sep 2020 17:57:54
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	(b) (4) System	10 Sep 2020 17:57:28
User entered 'cardiopulmonary arrest'	Brenda Anderson (b) (4)	02 Sep 2020 14:56:39
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:59:50

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 01:03:21
User entered '1 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:58:24

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:59:50

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 01:03:21
User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	10 Sep 2020 17:48:19
User entered 'Death (DEATH)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 17:48:19
User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	02 Sep 2020 14:58:24
User entered 'SAE (specify) (SAE)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:58:24

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:59:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 01:03:21
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	10 Sep 2020 17:48:32
User entered empty; reason for change Data Entry Error	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 17:48:32
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	10 Sep 2020 17:48:19
User entered 'cardiopulmonary arrest'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:58:24

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:59:50

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 01:03:21
User closed query 'Per CDM; please consider adding AE record number (i.e. Adverse Event #1 or AE#1)' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:24:08
Query 'Per CDM; please consider adding AE record number (i.e. Adverse Event #1 or AE#1)' answered with 'AE#1' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	21 Nov 2020 12:05:22
User opened query 'Per CDM; please consider adding AE record number (i.e. Adverse Event #1 or AE#1)' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:18:51
Query 'Per CDM: reason for discontinuation is recorded as Death, per CCGs please recorded AE record number. Update accordingly or clarify ' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:38:16
User opened query 'Per CDM: reason for discontinuation is recorded as Death, per CCGs please recorded AE record number. Update accordingly or clarify ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:49:45
User closed query 'Reason for discontinuation is Death, however main cause of death is missing. Please provide.' (Site from System).	System	10 Sep 2020 17:59:54
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Brenda Anderson (b) (4) (b) (4)	10 Sep 2020 17:59:54
User opened query 'Reason for discontinuation is Death, however main cause of death is missing. Please provide.' (Site from System).	System	10 Sep 2020 17:48:19
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:58:24

US3512042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:59:50

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 01:03:21
User entered empty.	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:58:24

US3512042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:59:50

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 01:03:21
User entered '1 Sep 2020'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:58:24

US3512042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:59:50

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 01:03:21
User entered 'Unknown (UNK)'	Brenda Anderson (b) (4) (b) (4)	02 Sep 2020 14:58:24

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'USA-US065-2020-MRNA-1273-P301000001'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Michael'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6) '	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Koren'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6) '	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6),'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:47:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 23:51:23
User entered (b) (6) (non-conformant).	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
User entered '3'	(b) (4)	20 Sep 2020 21:17:57
User entered '2'	System	02 Sep 2020 23:51:40
User entered '1'	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'USA-US065-2020-MRNA-1273-P301000001'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Michael'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6) '	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Koren'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6) '	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6),'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:47:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 23:51:23
User entered (b) (6) (non-conformant).	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
User entered '3'	(b) (4)	20 Sep 2020 21:17:57
User entered '2'	System	02 Sep 2020 23:51:40
User entered '1'	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:59:50

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
User entered '02/Sep/2020 14:18'	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:59:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 23:51:23
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'USA-US065-2020-MRNA-1273-P301000001'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Michael'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6) '	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Koren'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6) '	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6),'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:47:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 23:51:23
User entered (b) (6) (non-conformant).	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
User entered '3'	(b) (4)	20 Sep 2020 21:17:57
User entered '2'	System	02 Sep 2020 23:51:40
User entered '1'	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:59:50

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
User entered '02/Sep/2020 19:51'	System	02 Sep 2020 23:51:40

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:59:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
User entered 'I'	(b) (4), (b) (6)	02 Sep 2020 23:51:40

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'USA-US065-2020-MRNA-1273-P301000001'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'Yes (Y)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered 'No (N)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Michael'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6) '	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered 'Koren'	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6) '	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6),'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 21:17:45
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:50:15
Amendment Manager: User entered empty.	System	14 Sep 2020 21:50:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 18:18:34
User entered (b) (6)'	System	02 Sep 2020 18:17:12

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:47:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Sep 2020 23:51:23
User entered (b) (6) (non-conformant).	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:50

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
User entered '3'	(b) (4)	20 Sep 2020 21:17:57
User entered '2'	System	02 Sep 2020 23:51:40
User entered '1'	System	02 Sep 2020 18:18:41

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:59:50

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
User entered '20/Sep/2020 17:17'	System	20 Sep 2020 21:17:57

US3512042

Folder: SAE USA-US065-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:59:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:32:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 13:10:08
User entered '1'	(b) (4), (b) (6)	20 Sep 2020 21:17:57