

US3512082 (Prod: Jacksonville Center for Clinical Research Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:00:37

All time stamps listed in this document are displayed in GMT

US3512082

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 20:48:22

Generated On: 10 Jun 2021 08:00:37

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[Participant ID](#)

US3512082

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

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US3512082

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	68
Age Units	YEARS
Age (Derived)	68
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 20:48:24

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 20:48:24

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	SEASONAL 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 (2)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	TUBULAR ADENOMA OF THE TRANSVERSE COLON
Start date (dd MMM yyyy)	UN FEB 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN FEB 2011
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2011
Start Year (derived)	2011
Stop Month and Year (derived)	FEB 2011
Stop Year (derived)	2011

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	RADIATION PROCTITIS WITH INTERMITTENT BLEEDING
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
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 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	VITAMIN B12 DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 1993
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1993
Start Year (derived)	1993
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	HEARING LOSS BILATERAL
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
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 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	INTERMITTENT RASH IN EAR CANALS
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 (9)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	CONCUSSION
Start date (dd MMM yyyy)	UN UNK 1972
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1972
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1972
Start Year (derived)	1972
Stop Month and Year (derived)	JAN 1972
Stop Year (derived)	1972



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	TRANSIENT LEFT PERONEAL NERVE NEUROPATHY
Start date (dd MMM yyyy)	UN AUG 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2013
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2013
Start Year (derived)	2013
Stop Month and Year (derived)	AUG 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	SLEEP APNEA
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 (12)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	POST NASAL DRIP
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 (13)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	RECURRENT SUBACUTE SINUSITIS
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 (14)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	ROASACEA
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
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 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	BASAL CELL CARCINOMA ON BACK
Start date (dd MMM yyyy)	UN JUN 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2009
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JUN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	ONYCHOMYCOSIS
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 (17)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	BACK MUSCLE SPASMS
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 (18)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	BACK PAIN
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 (19)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	FRACTURED LEFT MIDDLE FINGER
Start date (dd MMM yyyy)	UN UNK 1966
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 1966
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1966
Start Year (derived)	1966
Stop Month and Year (derived)	JAN 1966
Stop Year (derived)	1966

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	NASAL FRACTURE
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 1991
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 1991
Start Year (derived)	1991
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 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	UN JUL 2008
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 JUL 2008
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JUL 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

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

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	HEART CATHETERIZATION
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: Medical History (26)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	PROSTATECTOMY
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

US3512082

Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	SURGICAL REPAIR OF LEFT MIDDLE FINGER
Start date (dd MMM yyyy)	UN UNK 1966
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 1966
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1966
Start Year (derived)	1966
Stop Month and Year (derived)	JAN 1966
Stop Year (derived)	1966

US3512082

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	CARDIAC STENTS INSERTED X3
Start date (dd MMM yyyy)	UN JUL 2008
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 JUL 2008
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JUL 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	CARDIAC STENTS INSERTED X3
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN JUL 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3512082

Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (32)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:50 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 13:50
Height ( <i>xxx.x</i> )	71 in
Weight ( <i>xxx.x</i> )	207 lb
BMI ( <i>xxx.x</i> )	28.93101 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 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 20:48:24

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 20:48:24

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	True
<b>Specify</b>	HAS ATTENDED LARGE GROUPS EVENTS IN THE PAST FEW WEEKS (WATER PARK, FAMILY GATHERING); ROUTINELY GOES TO PLACES WHERE PEOPLE GATHER (GROCERY, TARGET, HARDWARE STORE MULTIPLE TIMES A WEEK)

US3512082

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3512082

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 186318

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 ☒

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Height	ND - Not Done
Weight	ND - Not Done

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 13:50
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	15:38 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 15:38
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG



US3512082

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

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.*

US3512082

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 15:08 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 15:08

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

US3512082

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 AUG 2020
Collection time (00:00-23:59)	14:30 (24 HR)
Collection date and time (derived)	14 AUG 2020 14:30

US3512082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Collection date ( <i>dd MMM yyyy</i> )			14 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	14:18	14 AUG 2020 14:18
Nasopharyngeal Swab 2	No		

US3512082

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 15:35

PC Open Date & Time

14 AUG 2020 15:28

PC Close Date & Time

14 AUG 2020 17:58

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**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 97.5 °F

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

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

PC Time Stamp	14 AUG 2020 19:05
PC Open Date & Time	14 AUG 2020 18:53
PC Close Date & Time	15 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

15 AUG 2020 18:57

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59



US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 18:34

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:37

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

95.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

17 AUG 2020 18:32

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PC Open Date & Time

17 AUG 2020 12:00

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PC Close Date & Time

18 AUG 2020 11:59

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US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 18:25

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:37

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 19:22

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 17:54

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**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

14 AUG 2020 15:36

PC Open Date & Time

14 AUG 2020 15:28

PC Close Date & Time

14 AUG 2020 17:58

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**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

14 AUG 2020 19:07

PC Open Date & Time

14 AUG 2020 18:53

PC Close Date & Time

15 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 18:58

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59



US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 18:35

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 18:33

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 18:26

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 19:23

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 17:55

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**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 ☐

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 15:37
PC Open Date & Time	14 AUG 2020 15:28
PC Close Date & Time	14 AUG 2020 17:58

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**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 ☐



US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 19:08
PC Open Date & Time	14 AUG 2020 18:53
PC Close Date & Time	15 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:37

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 18:59
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:37

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 18:37
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**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 ☒

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 18:35
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:37

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 18:27
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:37

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 19:24
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**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 ☒

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:37

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 17:56
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3512082

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3512082

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3512082

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512082

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:48:25

Generated On: 10 Jun 2021 08:00:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:48:25

Generated On: 10 Jun 2021 08:00:37

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:00
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:48:25

Generated On: 10 Jun 2021 08:00:37

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:20
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3512082

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3512082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 13:49 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 13:49

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



US3512082

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	13:25 (24 HR)
Collection date and time (derived)	11 SEP 2020 13:25

US3512082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:16	11 SEP 2020 13:16
Nasopharyngeal Swab 2	No		

US3512082

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:24

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 14:24

PC Open Date & Time

11 SEP 2020 14:09

PC Close Date & Time

11 SEP 2020 16:39

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**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 96.5 °F

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

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

PC Time Stamp	11 SEP 2020 18:31
PC Open Date & Time	11 SEP 2020 17:34
PC Close Date & Time	12 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 18:24

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

13 SEP 2020 18:18

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 17:45

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 21:52

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 21:20

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 21:11

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**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

11 SEP 2020 14:25

PC Open Date & Time

11 SEP 2020 14:09

PC Close Date & Time

11 SEP 2020 16:39

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**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

11 SEP 2020 18:32

PC Open Date & Time

11 SEP 2020 17:34

PC Close Date & Time

12 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 18:26

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 18:19

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 17:46

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 21:53

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 21:20

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 21:11

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**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 ☐

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 14:26
PC Open Date & Time	11 SEP 2020 14:09
PC Close Date & Time	11 SEP 2020 16:39

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**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 ☐

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 18:32
PC Open Date & Time	11 SEP 2020 17:34
PC Close Date & Time	12 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:37

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 18:27
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:37

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 18:19
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 17:47
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:37

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 21:54
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:37

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 21:22
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:37

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 21:12
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3512082

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3512082

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512082

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3512082

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:48:25

Generated On: 10 Jun 2021 08:00:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3512082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:48:25

Generated On: 10 Jun 2021 08:00:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	9 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	13:00 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 13:00
Temperature ( <i>xxx.x</i> )	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	56 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3512082

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:48:25

Generated On: 10 Jun 2021 08:00:37

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.*

US3512082

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:48:25

Generated On: 10 Jun 2021 08:00:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 OCT 2020
Collection time (00:00-23:59)	13:15 (24 HR)
Collection date and time (derived)	9 OCT 2020 13:15

US3512082

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:25

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 OCT 2020 12:11:07
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 OCT 2020 09:31:33
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59



US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 09:43:58
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 11:12:58

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 09:49:51
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 17:07:43
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 17:54:51

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 11:30:07
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 09:11:26

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 19:57:25
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59



US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 19:53:01

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 11:46:15

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 22:46:58

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 22:24:57
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 08:09:43

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 10:46:49

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	31 JAN 2021 16:07:23
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 FEB 2021 12:01:01
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59



US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

<b>TIMEPOINT</b>	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 04:14:15
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 08:44:33

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	28 FEB 2021 12:26:47
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 09:05:35

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 12:32:34

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 18:25:46

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 08:05:16

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 07:54:50

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59



US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	11 APR 2021 22:14:29
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 08:44:21

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 APR 2021 19:24:17
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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02 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAY 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUN 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 JUL 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 SEP 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59
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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 FEB 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 FEB 2022 23:59
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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 APR 2022 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

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



**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2022 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

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

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

**US3512082**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2022 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq$  100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
Chills ☐  
Cough ☐  
Shortness of breath ☐  
Difficulty breathing ☐  
Fatigue ☐  
Muscle aches ☐  
Body aches ☐  
Headache ☐  
New loss of taste ☐  
New loss of smell ☐  
Sore throat ☐  
Congestion ☐  
Runny nose ☐  
Nausea ☐  
Vomiting ☐  
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐  
Yes ☐

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3512082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2022 23:59

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US3512082

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:00:37

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 12:27:06

US3512082

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512082

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3512082

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512082

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512082

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 FEB 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512082

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 22:40:36

Generated On: 10 Jun 2021 08:00:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3512082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 17:29:43

Generated On: 10 Jun 2021 08:00:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	03 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	10:03 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 10:03
Temperature ( <i>xxx.x</i> )	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	82 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3512082

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 17:29:43

Generated On: 10 Jun 2021 08:00:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 MAR 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3512082

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 22:40:36

Generated On: 10 Jun 2021 08:00:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 MAR 2021
Collection time (00:00-23:59)	10:32 (24 HR)
Collection date and time (derived)	3 MAR 2021 10:32

US3512082

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:40:36

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 12:02:55

Generated On: 10 Jun 2021 08:00:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512082

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 12:02:55

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3512082**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

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*

**US3512082**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3512082**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 08:00:37**

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"/>



**US3512082**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 08:00:37**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 12:45:59

Generated On: 10 Jun 2021 08:00:37

Date of updated informed consent ( <i>dd MMM yyyy</i> )	22 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Height	71 in
Weight	206 lb
BMI (xxx.x)	28.79124

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Height	71 in
Weight	206 lb
BMI (xxx.x)	28.79124
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	10:31 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 10:31
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Height	71 in
Weight	206 lb
BMI (xxx.x)	28.79124
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	12:09 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 12:09
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

22 JAN 2021

---

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

---

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 11:35 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 11:35

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



US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

10:45 (24 HR)

Collection date and time (derived)

22 JAN 2021 10:45

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	10:53
Collection Date and Time (derived)	22 JAN 2021 10:53

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512082

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3512082

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 22:40:36

Generated On: 10 Jun 2021 08:00:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3512082

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 22:40:36

Generated On: 10 Jun 2021 08:00:37

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 MAR 2021
Time of assessment (00:00-23:59)	10:03 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 10:03
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3512082

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 22:40:36

Generated On: 10 Jun 2021 08:00:37

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	3 MAR 2021
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 11:48
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG



US3512082

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 22:40:36

Generated On: 10 Jun 2021 08:00:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 MAR 2021

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

US3512082

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 22:40:36

Generated On: 10 Jun 2021 08:00:37

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 3 MAR 2021

What was the treatment time? (00:00-23:59) 11:15 (24 HR)

Treatment Date and Time (derived) 3 MAR 2021 11:15

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

US3512082

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:40:36

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 12:45:59

Generated On: 10 Jun 2021 08:00:37

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 MAR 2021

Please select one status for the follow-up contact  
Contact Made ☒  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3512082

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 12:45:59

Generated On: 10 Jun 2021 08:00:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3512082

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 19:27:42

Generated On: 10 Jun 2021 08:00:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3512082

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 19:27:42

Generated On: 10 Jun 2021 08:00:37

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3512082

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 19:27:42

Generated On: 10 Jun 2021 08:00:37

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.*



US3512082

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 19:27:42

Generated On: 10 Jun 2021 08:00:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 MAR 2021
Collection time (00:00-23:59)	10:26 (24 HR)
Collection date and time (derived)	31 MAR 2021 10:26

US3512082

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 20:48:22

Generated On: 10 Jun 2021 08:00:37

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3512082

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

AEID	
Adverse event	EXERCISE WORSENER BACK MUSCLE SPASMS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 OCT 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)	29 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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"/>

US3512082

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3512082

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

AEID	
Adverse event	RIGHT HORDEOLUM
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 NOV 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	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3512082

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

AEID	
Adverse event	LEFT HORDEOLUM
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	4 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 NOV 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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

AEID	USA-US065-2021-MRNA-1273-P30 1000004
Adverse event	ACUTE URINARY RETENTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	07 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	2 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	4 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	CHRONIC URINARY RETENTION - MODERATE
Narrative	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

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FIRST REPORTED TO  
EMERGENCY ROOM 1/26/21  
WITH HEMATURIA/URINARY  
RETENTION. TREATED WITH  
INDWELLING CATHETER AND  
BACTRIM DS. FOLLOW UP  
WITH UROLOGY CLINIC  
SCHEDULED FOR "TRIAL OF  
VOID" AND CATHETER  
REMOVAL.

HAD TO RETURN TO ER ON  
1/27/21 AND 02/02/21 DUE TO  
CLOTS IN CATHETER CAUSING  
ACUTE URINARY RETENTION.  
ADMITTED 2/2/21 FOR  
CONTINUOUS LAVAGE.  
DISCHARGED ON 02/04/21 WITH  
INDWELLING CATHETER AND  
EQUIPMENT FOR AT HOME  
LAVAGE. CONCERN WAS THAT  
FINDINGS MAY HAVE BEEN  
RELATED TO THE PAST  
RADIATION THERAPY IN 2007  
FOR PROSTATE CANCER AND  
EXACERBATED BY THE  
EFFIENT AND ASPIRIN TAKEN  
FOR HEART DISEASE. EFFIENT  
WAS DISCONTINUED AND  
ASPIRIN WAS DECREASED TO  
EVERY OTHER DAY AFTER  
CONSULTATION WITH  
CARDIOLOGY. FURTHER  
WORKUP SCHEDULED.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

AEID	
Adverse event	ESCHERICHIA COLI INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

AEID	
Adverse event	KIDNEY STONE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

AEID	USA-US065-2021-MRNA-1273-P30 1000004
Adverse event	HEMATURIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	08 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	02 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	04 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 21:04:29

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

FIRST REPORTED TO  
EMERGENCY ROOM 1/27/21  
WITH HEMATURIA/URINARY  
RETENTION. TREATED WITH  
INDWELLING CATHETER AND  
BACTRIM DS. FOLLOW UP  
WITH UROLOGY CLINIC  
SCHEDULED FOR "TRIAL OF  
VOID" AND CATHETER  
REMOVAL.

HAD TO RETURN TO ER ON  
1/27/21 AND 02/02/21 DUE TO  
CLOTS IN CATHETER CAUSING  
ACUTE URINARY RETENTION.  
ADMITTED 2/2/21 FOR  
CONTINUOUS LAVAGE.  
DISCHARGED ON 02/04/21 WITH  
INDWELLING CATHETER AND  
EQUIPMENT FOR AT HOME  
LAVAGE. CONCERN WAS THAT  
FINDINGS MAY HAVE BEEN  
RELATED TO THE PAST  
RADIATION THERAPY IN 2007  
FOR PROSTATE CANCER AND  
EXACERBATED BY THE  
EFFIENT AND ASPIRIN TAKEN  
FOR HEART DISEASE. EFFIENT  
WAS DISCONTINUED AND  
ASPIRIN WAS DECREASED TO  
EVERY OTHER DAY AFTER  
CONSULTATION WITH  
CARDIOLOGY. FURTHER  
WORKUP SCHEDULED.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

AEID	
Adverse event	CHRONIC URINARY RETENTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT REQUIRES SELF-CATH BID
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3512082

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

AEID	
Adverse event	URINARY TRACT INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 20:48:23

Generated On: 10 Jun 2021 08:00:37

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIOPROTECTIVE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	03 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☒  
No ☐

Indication PREVENTATIVE DUE TO  
ASPIRIN USE

Dose per administration 40

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2008
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:04:29

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 80

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication PRASUGREL (EFFIENT)

Prophylaxis Yes ☐  
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	03 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:04:29

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Name of Medication METRONIDAZOLE 1%

Prophylaxis Yes ☐  
No ☒

Indication ROSACEA

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	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 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication VITAMIN B12

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN B12 DEFICIENCY

Dose per administration 2500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication FLUOCINOLONE ACETONIDE  
0.01%

Prophylaxis Yes ☐  
No ☒

Indication RASH IN EAR CANALS

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRAOTIC	
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication FEXOFENADINE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication DOCUSATE CALCIUM

Prophylaxis Yes ☒  
No ☐

Indication CONSTIPATION

Dose per administration 240

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☒  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	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 2007
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication DICLOFENAC 1%

Prophylaxis Yes ☐  
No ☒

Indication BACK PAIN

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication BACK PAIN

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:04:29

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Name of Medication FLUTICASONE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

Dose unit mg ☐  
ug ☒  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:04:29

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication AZELASTINE HYDROCHLORIDE  
0.1%

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☒  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication HYDROCORTISONE 1%

Prophylaxis Yes ☐  
No ☒

Indication RASH IN EAR CANALS

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	EXTERNAL AUDITORY CANALS	
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication TADALAFIL

Prophylaxis Yes ☐  
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication METHYLPREDNISOLONE  
SUCCINATE

Prophylaxis Yes ☐  
No ☒

Indication EXERCISE WORSENE D BACK  
MUSCLE SPASMS

Dose per administration 125

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 21:04:29

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	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication ROBAXIN

Prophylaxis Yes ☐  
No ☒

Indication BACK MUSCLE SPASMS

Dose per administration 750

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☒  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication ERYTHROMYCIN .5%

Prophylaxis Yes ☐  
No ☒

Indication RIGHT HORDEOLUM

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication ERYTHROMYCIN .5%

Prophylaxis Yes ☐  
No ☒

Indication LEFT HORDEOLUM

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication CARBOXYMETHYLCELLULOSE  
SODIUM 0.5%

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL HORDEOLUM

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify DROP PER EYE

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intraocular	<input checked="" type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication AUGMENTIN (AMOXICILLIN / CLAVULANIC ACID)

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL HORDEOLUM

Dose per administration 875/ 125

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	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)	4 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication SHINGLES VACCINE

Prophylaxis Yes ☒  
No ☐

Indication SHINGLES PROPHYLAXIS

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify INJECTION

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication BACTRIM DS

Prophylaxis Yes ☐  
No ☒

Indication ACUTE URINARY RETENTION

Dose per administration 400-80

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 2 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication PYRIDIUM ORAL

Prophylaxis Yes ☐  
No ☒

Indication ACUTE URINARY RETENTION

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	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)	2 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication TYLENOL

Prophylaxis Yes ☒  
No ☐

Indication INJECTION REACTION  
PROPHYLAXIS

Dose per administration 1000

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	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)		3 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		3 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIOPROTECTIVE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	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)		04 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		2
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication MACRODANTIN

Prophylaxis Yes ☐  
No ☒

Indication ESCHERICHIA COLI INFECTION

Dose per administration 100

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		24 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

Name of Medication NITROFURANTOIN

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 21:04:29

Generated On: 10 Jun 2021 08:00:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Mar 2021 20:41:29

Generated On: 10 Jun 2021 08:00:37

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 31 Mar 2021 17:29:43

Generated On: 10 Jun 2021 08:00:37

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 JAN 2021	INDWELLING CATHETERIZATION	Adverse Event	
4 FEB 2021	INDWELLING CATHETERIZATION	Adverse Event	
02 FEB 2021	CONTINUOUS BLADDER LAVAGE	Adverse Event	

US3512082

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:00:37

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3512082

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:00:37

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 14 Apr 2021 16:39:32

Generated On: 10 Jun 2021 08:00:37

SAEID	USA-US065-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5



US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 14 Apr 2021 16:39:32

Generated On: 10 Jun 2021 08:00:37

SAEID	USA-US065-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	11/FEB/2021 12:19
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

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 14 Apr 2021 16:39:32

Generated On: 10 Jun 2021 08:00:37

SAEID	USA-US065-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	17/MAR/2021 12:51
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.	True

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 14 Apr 2021 16:39:32

Generated On: 10 Jun 2021 08:00:37

SAEID	USA-US065-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	29/MAR/2021 15:49
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.	False

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 14 Apr 2021 16:39:32

Generated On: 10 Jun 2021 08:00:37

SAEID	USA-US065-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	30/MAR/2021 09:35
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

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 14 Apr 2021 16:39:32

Generated On: 10 Jun 2021 08:00:37

SAEID	USA-US065-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	01/APR/2021 09:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 14 Apr 2021 16:39:32

Generated On: 10 Jun 2021 08:00:37

SAEID	USA-US065-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	5
Date of submission (Pre-filled from custom function)	08/APR/2021 18:05
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

US3512082 (Prod: Jacksonville Center for Clinical Research Center)

**US3512082**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 08:00:37**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'US3512082'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:20:28



**US3512082**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:24

**US3512082**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:20:30

US3512082

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:00:37

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Clinic (Clinic)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:24

**US3512082**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'SCRN'	System	14 Aug 2020 23:40:24

**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered (b) (6) 1952'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:20:30

**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '68'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:57

**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'YEARS'	System	14 Aug 2020 23:40:57

**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '68'	System	14 Aug 2020 19:17:12



**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Male (M)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:57

US3512082

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:00:37

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:57

**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'I'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:57

**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:57

**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:57

**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:57

**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:57

**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:57



**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:57

**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:57

**US3512082**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 08:00:37**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:40:57

US3512082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:37

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '14 Aug 2020'	Brenda Anderson (b) (4)	14 Aug 2020 19:17:12

**US3512082**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:00:37**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Aug 2020'	System	14 Aug 2020 19:17:12

**US3512082**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:00:37**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2020'	System	14 Aug 2020 19:17:12

**US3512082**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:00:37**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Amendment 2 (2)'	Brenda Anderson (b) (4)	14 Aug 2020 19:17:12

US3512082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:37

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	14 Aug 2020 19:17:12



US3512082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:37

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Brenda Anderson (b) (4)	14 Aug 2020 19:17:12

US3512082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:37

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Brenda Anderson (b) (4)	14 Aug 2020 19:17:12

US3512082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:37

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Brenda Anderson (b) (4)	14 Aug 2020 19:17:12

US3512082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:37

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:20:30

**US3512082**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 08:00:37**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'I'	System	14 Aug 2020 19:17:19

US3512082

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:00:37

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	14 Aug 2020 19:17:19

**US3512082**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 08:00:37**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:41:03

US3512082

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:59
Data point term sent to Coder	System	14 Aug 2020 23:43:01
User entered 'seasonal allergies'	Taylor Johnson (b) (4)	14 Aug 2020 23:42:23



US3512082

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2000'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:42:23

**US3512082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:42:23

**US3512082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:42:23

**US3512082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:42:23

**US3512082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:42:23

**US3512082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2000'	System	14 Aug 2020 23:42:23

**US3512082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2000'	System	14 Aug 2020 23:42:23

**US3512082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:42:23



**US3512082**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:42:23

US3512082

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms benign, HLT: Lower gastrointestinal neoplasms benign, PT: Colon adenoma, LLT: Colonic tubular adenoma - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 06:00:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 06:00:10
Data point term sent to Coder	System	14 Aug 2020 23:45:03
User entered 'tubular adenoma of the transverse colon'	Taylor Johnson (b) (4)	14 Aug 2020 23:44:11

**US3512082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un Feb 2011'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:44:11

**US3512082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:44:11

**US3512082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:44:11

**US3512082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un Feb 2011'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:44:11

**US3512082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:44:11

**US3512082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Feb 2011'	System	14 Aug 2020 23:44:11



**US3512082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2011'	System	14 Aug 2020 23:44:11

**US3512082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Feb 2011'	System	14 Aug 2020 23:44:11

**US3512082**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2011'	System	14 Aug 2020 23:44:11

US3512082

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries by physical agents, HLT: Radiation injuries, PT: Radiation proctitis, LLT: Radiation proctitis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 12:06:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 12:06:27
Data point term sent to Coder	System	14 Aug 2020 23:46:06
User entered 'radiation proctitis with intermittent bleeding'	Taylor Johnson (b) (4)	14 Aug 2020 23:45:30

US3512082

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2007'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:45:30

**US3512082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:45:30

**US3512082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:45:30

**US3512082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2007'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:45:30



**US3512082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:45:30

**US3512082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2007'	System	14 Aug 2020 23:45:30

**US3512082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2007'	System	14 Aug 2020 23:45:30

**US3512082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2007'	System	14 Aug 2020 23:45:30

**US3512082**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2007'	System	14 Aug 2020 23:45:30

US3512082

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Reproductive system and breast disorders, HLGT: 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)	15 Aug 2020 00:23:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:01
Data point term sent to Coder	System	14 Aug 2020 23:46:06
User entered 'erectile dysfunction'	Taylor Johnson (b) (4)	14 Aug 2020 23:45:57

US3512082

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2007'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:45:57

**US3512082**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:45:57



US3512082

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:00:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	15 Aug 2020 16:23:29
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	14 Aug 2020 23:45:57
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	14 Aug 2020 23:45:57

US3512082

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:00:37

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty; reason for change Data Entry Error	(b) (4)	
	Taylor Johnson (b) (4)	15 Aug 2020 16:23:29
User entered 'un UNK 2007'	(b) (4)	
	Taylor Johnson (b) (4)	14 Aug 2020 23:45:57
	(b) (4)	

**US3512082**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:45:57

**US3512082**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2007'	System	14 Aug 2020 23:45:57

**US3512082**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2007'	System	14 Aug 2020 23:45:57

**US3512082**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	15 Aug 2020 16:23:29
User entered 'Jan 2007'	System	14 Aug 2020 23:45:57

**US3512082**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	15 Aug 2020 16:23:29
User entered '2007'	System	14 Aug 2020 23:45:57

US3512082

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Vitamin B12 deficiency, LLT: Vitamin B12 deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:02
Data point term sent to Coder	System	14 Aug 2020 23:48:07
User entered 'vitamin b12 deficiency'	Taylor Johnson (b) (4)	14 Aug 2020 23:47:28



US3512082

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2014'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:47:28

**US3512082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:47:28

**US3512082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:47:28

**US3512082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:47:28

**US3512082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:47:28

**US3512082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2014'	System	14 Aug 2020 23:47:28

**US3512082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2014'	System	14 Aug 2020 23:47:28

**US3512082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:47:28



**US3512082**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:47:28

US3512082

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:02
Data point term sent to Coder	System	14 Aug 2020 23:48:07
User entered 'presbyopia'	Taylor Johnson (b) (4)	14 Aug 2020 23:47:50

**US3512082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 1993'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:47:50

**US3512082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:47:50

**US3512082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:47:50

**US3512082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:47:50

**US3512082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:47:50

**US3512082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 1993'	System	14 Aug 2020 23:47:50



**US3512082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '1993'	System	14 Aug 2020 23:47:50

**US3512082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:47:50

**US3512082**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:47:50

US3512082

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:00:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per DM CLR: Please specify the laterality of HEARING LOSS (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 03:33:58
' (Site from DM).		
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)	01 Oct 2020 23:47:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 23:47:54
Data point term sent to Coder	System	01 Oct 2020 23:47:10
Query 'Per DM CLR: Please specify the laterality of HEARING LOSS (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 23:46:34
' answered with 'data updated' (Site from DM).		
Coding entries removed.	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 23:46:23
User entered 'HEARING LOSS bilateral' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 23:46:23
User opened query 'Per DM CLR: Please specify the laterality of HEARING LOSS (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable.	(b) (4), (b) (6)	27 Sep 2020 16:05:46
' (Site from DM).		
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)	15 Aug 2020 00:23:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:23:03
Data point term sent to Coder	System	14 Aug 2020 23:49:10
User entered 'hearing loss'	Taylor Johnson (b) (4) (b) (4)	14 Aug 2020 23:48:17

**US3512082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 1980'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:17

**US3512082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:17

**US3512082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:17

**US3512082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:17



**US3512082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:17

**US3512082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 1980'	System	14 Aug 2020 23:48:17

**US3512082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '1980'	System	14 Aug 2020 23:48:17

**US3512082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:48:17

**US3512082**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:48:17

US3512082

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 09:55:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 09:55:14
Data point term sent to Coder	System	14 Aug 2020 23:49:10
User entered 'intermittent rash in ear canals'	Taylor Johnson (b) (4)	14 Aug 2020 23:48:36

**US3512082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2000'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:36

**US3512082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:36



**US3512082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:36

**US3512082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:36

**US3512082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:36

**US3512082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2000'	System	14 Aug 2020 23:48:36

**US3512082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2000'	System	14 Aug 2020 23:48:36

**US3512082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:48:36

**US3512082**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:48:36

US3512082

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cerebral injuries NEC, PT: Concussion, LLT: Concussion - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:02
Data point term sent to Coder	System	14 Aug 2020 23:49:09
User entered 'concussion'	Taylor Johnson (b) (4)	14 Aug 2020 23:48:59



US3512082

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 1972'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:59

**US3512082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:59

**US3512082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:59

**US3512082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 1972'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:59

**US3512082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:48:59

**US3512082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 1972'	System	14 Aug 2020 23:48:59

**US3512082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '1972'	System	14 Aug 2020 23:48:59

**US3512082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 1972'	System	14 Aug 2020 23:48:59



**US3512082**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '1972'	System	14 Aug 2020 23:48:59

US3512082

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:00:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per DM CLR: Please specify the laterality of TRANSIENT LEFT PERONEAL NERVE NEUROPATHY (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 03:34:13
Query 'Per DM CLR: Please specify the laterality of TRANSIENT LEFT PERONEAL NERVE NEUROPATHY (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. ' answered with 'data confirmed as is. laterality was already noted' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 23:47:24
User opened query 'Per DM CLR: Please specify the laterality of TRANSIENT LEFT PERONEAL NERVE NEUROPATHY (left, right, bilateral). Review and update MH condition as appropriate and ensure update is reconciled with any corresponding ConMed/AE entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 16:06:22
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 09:28:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 09:28:41
Data point term sent to Coder	System	14 Aug 2020 23:50:10
User entered 'transient left peroneal nerve neuropathy'	Taylor Johnson (b) (4) (b) (4)	14 Aug 2020 23:49:49

**US3512082**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un Aug 2013'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:49:49

**US3512082**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:49:49

**US3512082**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:49:49

**US3512082**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un Aug 2013'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:49:49

**US3512082**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:49:49

**US3512082**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Aug 2013'	System	14 Aug 2020 23:49:49



**US3512082**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2013'	System	14 Aug 2020 23:49:49

**US3512082**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Aug 2013'	System	14 Aug 2020 23:49:49

**US3512082**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2013'	System	14 Aug 2020 23:49:49

US3512082

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:03
Data point term sent to Coder	System	14 Aug 2020 23:50:10
User entered 'sleep apnea'	Taylor Johnson (b) (4)	14 Aug 2020 23:50:03

**US3512082**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2019'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:50:03

**US3512082**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:50:03

**US3512082**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:50:03

**US3512082**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:50:03



**US3512082**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:50:03

**US3512082**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2019'	System	14 Aug 2020 23:50:03

**US3512082**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2019'	System	14 Aug 2020 23:50:03

**US3512082**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:50:03

**US3512082**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:50:03

US3512082

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:00:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Upper-airway cough syndrome, LLT: Postnasal drip - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:03
Data point term sent to Coder	System	14 Aug 2020 23:52:13
User entered 'post nasal drip'	Taylor Johnson (b) (4)	14 Aug 2020 23:51:38

US3512082

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2000'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:51:38

**US3512082**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:51:38



**US3512082**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:51:38

**US3512082**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:51:38

**US3512082**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:51:38

**US3512082**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2000'	System	14 Aug 2020 23:51:38

**US3512082**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2000'	System	14 Aug 2020 23:51:38

**US3512082**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:51:38

**US3512082**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:51:38

US3512082

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 08:00:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis recurrent - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:27:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:27:17
Data point term sent to Coder	System	14 Aug 2020 23:53:16
User entered 'recurrent subacute sinusitis'	Taylor Johnson (b) (4)	14 Aug 2020 23:52:51



**US3512082**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2000'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:52:51

**US3512082**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:52:51

**US3512082**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:52:51

**US3512082**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:52:51

**US3512082**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:52:51

**US3512082**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2000'	System	14 Aug 2020 23:52:51

**US3512082**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2000'	System	14 Aug 2020 23:52:51

**US3512082**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:52:51



**US3512082**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:52:51

US3512082

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 06:21:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 06:21:18
Data point term sent to Coder	System	14 Aug 2020 23:53:16
User entered 'roasacea'	Taylor Johnson (b) (4)	14 Aug 2020 23:53:05

**US3512082**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2006'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:53:05

**US3512082**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:53:05

**US3512082**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:53:05

**US3512082**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:53:05

US3512082

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 08:00:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:53:05

**US3512082**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2006'	System	14 Aug 2020 23:53:05



**US3512082**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2006'	System	14 Aug 2020 23:53:05

**US3512082**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:53:05

**US3512082**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:53:05

US3512082

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 05:45:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 05:45:10
Data point term sent to Coder	System	14 Aug 2020 23:54:17
User entered 'basal cell carcinoma on back'	Taylor Johnson (b) (4)	14 Aug 2020 23:53:43

US3512082

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un Jun 2009'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:53:43

**US3512082**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:53:43

**US3512082**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:53:43

**US3512082**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un Jun 2009'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:53:43



**US3512082**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:53:43

**US3512082**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jun 2009'	System	14 Aug 2020 23:53:43

**US3512082**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2009'	System	14 Aug 2020 23:53:43

**US3512082**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jun 2009'	System	14 Aug 2020 23:53:43

**US3512082**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2009'	System	14 Aug 2020 23:53:43

US3512082

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 08:00:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per DM CLR: Please specify the location of ONYCHOMYCOSIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 03:34:27
' (Site from DM).		
Query 'Per DM CLR: Please specify the location of ONYCHOMYCOSIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	02 Oct 2020 16:12:49
' answered with 'Bilateral Feet' (Site from DM).		
User opened query 'Per DM CLR: Please specify the location of ONYCHOMYCOSIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	27 Sep 2020 16:06:49
' (Site from DM).		
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Onychomycosis, LLT: Onychomycosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:23:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:23:04
Data point term sent to Coder	System	14 Aug 2020 23:55:17
User entered 'onychomycosis'	Taylor Johnson (b) (4) (b) (4)	14 Aug 2020 23:54:39

**US3512082**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2000'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:54:39

**US3512082**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:54:39



**US3512082**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:54:39

**US3512082**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:00:37**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:54:39

**US3512082**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:54:39

**US3512082**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2000'	System	14 Aug 2020 23:54:39

**US3512082**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2000'	System	14 Aug 2020 23:54:39

**US3512082**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:54:39

**US3512082**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:54:39

US3512082

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:05
Data point term sent to Coder	System	14 Aug 2020 23:55:18
User entered 'back muscle spasms'	Taylor Johnson (b) (4)	14 Aug 2020 23:55:03



**US3512082**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2010'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:55:03

**US3512082**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:55:03

**US3512082**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:55:03

**US3512082**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:55:03

**US3512082**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:55:03

**US3512082**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2010'	System	14 Aug 2020 23:55:03

**US3512082**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2010'	System	14 Aug 2020 23:55:03

**US3512082**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:55:03



**US3512082**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:55:03

US3512082

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 08:00:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:05
Data point term sent to Coder	System	14 Aug 2020 23:56:18
User entered 'back pain'	Taylor Johnson (b) (4)	14 Aug 2020 23:55:25

**US3512082**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2010'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:55:25

**US3512082**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:55:25

**US3512082**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:55:25

**US3512082**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:00:37**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:55:25

**US3512082**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:55:25

**US3512082**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2010'	System	14 Aug 2020 23:55:25



**US3512082**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2010'	System	14 Aug 2020 23:55:25

**US3512082**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:55:25

**US3512082**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:55:25

US3512082

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hand fracture, LLT: Fractured finger - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 08:34:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 08:34:10
Data point term sent to Coder	System	14 Aug 2020 23:56:19
User entered 'fractured left middle finger'	Taylor Johnson (b) (4)	14 Aug 2020 23:56:03

US3512082

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 1966'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:56:03

**US3512082**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:56:03

**US3512082**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:56:03

**US3512082**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 1966'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:56:03



**US3512082**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:56:03

**US3512082**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 1966'	System	14 Aug 2020 23:56:03

**US3512082**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '1966'	System	14 Aug 2020 23:56:03

**US3512082**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 1966'	System	14 Aug 2020 23:56:03

**US3512082**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '1966'	System	14 Aug 2020 23:56:03

US3512082

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 08:00:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Fractured nose - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:05
Data point term sent to Coder	System	14 Aug 2020 23:57:19
User entered 'nasal fracture'	Taylor Johnson (b) (4)	14 Aug 2020 23:56:23

**US3512082**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 1980'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:56:23

**US3512082**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:56:23



**US3512082**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:56:23

**US3512082**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 1980'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:56:23

**US3512082**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:56:23

**US3512082**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 1980'	System	14 Aug 2020 23:56:23

**US3512082**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '1980'	System	14 Aug 2020 23:56:23

**US3512082**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 1980'	System	14 Aug 2020 23:56:23

**US3512082**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '1980'	System	14 Aug 2020 23:56:23

US3512082

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:05
Data point term sent to Coder	System	14 Aug 2020 23:57:20
User entered 'hypercholesterolemia'	Taylor Johnson (b) (4)	14 Aug 2020 23:57:10



**US3512082**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 1991'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:57:10

**US3512082**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:57:10

**US3512082**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:57:10

**US3512082**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:57:10

**US3512082**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:57:10

**US3512082**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 1991'	System	14 Aug 2020 23:57:10

**US3512082**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '1991'	System	14 Aug 2020 23:57:10

**US3512082**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:57:10



**US3512082**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	14 Aug 2020 23:57:10

US3512082

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:06
Data point term sent to Coder	System	14 Aug 2020 23:58:20
User entered 'prostate cancer'	Taylor Johnson (b) (4)	14 Aug 2020 23:57:33

US3512082

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2007'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:57:33

**US3512082**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:57:33

**US3512082**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:57:33

**US3512082**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2007'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:57:33

**US3512082**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:57:33

**US3512082**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2007'	System	14 Aug 2020 23:57:33



**US3512082**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2007'	System	14 Aug 2020 23:57:33

**US3512082**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2007'	System	14 Aug 2020 23:57:33

**US3512082**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2007'	System	14 Aug 2020 23:57:33

US3512082

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:07
Data point term sent to Coder	System	14 Aug 2020 23:59:21
User entered 'myocardial infarction'	Taylor Johnson (b) (4)	14 Aug 2020 23:58:27

US3512082

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un Jul 2008'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:58:27

US3512082

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 08:00:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:58:27

**US3512082**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:58:27

**US3512082**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un Jul 2008'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:58:27



**US3512082**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:58:27

**US3512082**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jul 2008'	System	14 Aug 2020 23:58:27

**US3512082**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2008'	System	14 Aug 2020 23:58:27

**US3512082**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jul 2008'	System	14 Aug 2020 23:58:27

**US3512082**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2008'	System	14 Aug 2020 23:58:27

US3512082

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:07
Data point term sent to Coder	System	14 Aug 2020 23:59:22
User entered 'myocardial infarction'	Taylor Johnson (b) (4)	14 Aug 2020 23:59:04

US3512082

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2015'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:59:04

US3512082

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:00:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:59:04



**US3512082**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:59:04

**US3512082**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2015'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:59:04

US3512082

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 08:00:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	14 Aug 2020 23:59:04

**US3512082**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2015'	System	14 Aug 2020 23:59:04

**US3512082**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2015'	System	14 Aug 2020 23:59:04

**US3512082**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2015'	System	14 Aug 2020 23:59:04

**US3512082**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2015'	System	14 Aug 2020 23:59:04

US3512082

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac imaging procedures, PT: Catheterisation cardiac, LLT: Cardiac catheterization - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:08
Data point term sent to Coder	System	15 Aug 2020 00:01:31
User entered 'heart catheterization'	Taylor Johnson (b) (4)	15 Aug 2020 00:00:47



US3512082

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un Dec 2019'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:00:47

**US3512082**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:00:47

**US3512082**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:00:47

**US3512082**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un Dec 2019'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:00:47

**US3512082**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:00:47

**US3512082**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Dec 2019'	System	15 Aug 2020 00:00:47

**US3512082**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2019'	System	15 Aug 2020 00:00:47

**US3512082**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Dec 2019'	System	15 Aug 2020 00:00:47



**US3512082**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2019'	System	15 Aug 2020 00:00:47

US3512082

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatectomy, LLT: Prostatectomy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:23:42
Data point term sent to Coder	System	15 Aug 2020 00:02:32
User entered 'Prostatectomy'	Taylor Johnson (b) (4)	15 Aug 2020 00:01:33

US3512082

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2007'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:01:33

**US3512082**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:01:33

**US3512082**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:01:33

**US3512082**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2007'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:01:33

**US3512082**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:01:33

**US3512082**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2007'	System	15 Aug 2020 00:01:33



**US3512082**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2007'	System	15 Aug 2020 00:01:33

**US3512082**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2007'	System	15 Aug 2020 00:01:33

**US3512082**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2007'	System	15 Aug 2020 00:01:33

US3512082

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Finger repair operation, LLT: Finger repair operation - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:39:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 09:39:36
Data point term sent to Coder	System	15 Aug 2020 00:02:33
User entered 'surgical repair of left middle finger'	Taylor Johnson (b) (4)	15 Aug 2020 00:02:25

**US3512082**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 1966'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:02:25

**US3512082**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:02:25

**US3512082**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:02:25

**US3512082**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 1966'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:02:25



**US3512082**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:02:25

**US3512082**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 1966'	System	15 Aug 2020 00:02:25

**US3512082**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '1966'	System	15 Aug 2020 00:02:25

**US3512082**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 1966'	System	15 Aug 2020 00:02:25

**US3512082**

**Folder: Screening**

**Form: Medical History (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '1966'	System	15 Aug 2020 00:02:25

US3512082

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 14:16:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 14:16:19
Data point term sent to Coder	System	15 Aug 2020 00:03:34
User entered 'cardiac stents inserted x3'	Taylor Johnson (b) (4)	15 Aug 2020 00:03:05

**US3512082**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un Jul 2008'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:03:05

**US3512082**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:03:05



**US3512082**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:03:05

**US3512082**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un Jul 2008'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:03:05

US3512082

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 08:00:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:03:05

**US3512082**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jul 2008'	System	15 Aug 2020 00:03:05

**US3512082**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2008'	System	15 Aug 2020 00:03:05

**US3512082**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jul 2008'	System	15 Aug 2020 00:03:05

**US3512082**

**Folder: Screening**

**Form: Medical History (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2008'	System	15 Aug 2020 00:03:05

US3512082

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 14:16:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 14:16:19
Data point term sent to Coder	System	15 Aug 2020 00:04:35
User entered 'cardiac stents inserted x3'	Taylor Johnson (b) (4)	15 Aug 2020 00:03:52



**US3512082**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2015'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:03:52

**US3512082**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:03:52

**US3512082**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:03:52

**US3512082**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2015'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:03:52

**US3512082**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:03:52

**US3512082**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2015'	System	15 Aug 2020 00:03:52

**US3512082**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2015'	System	15 Aug 2020 00:03:52

**US3512082**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2015'	System	15 Aug 2020 00:03:52



**US3512082**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2015'	System	15 Aug 2020 00:03:52

US3512082

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:57:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:57:16
Data point term sent to Coder	System	15 Aug 2020 00:56:18
User entered 'Coronary artery disease'	Taylor Johnson (b) (4)	15 Aug 2020 00:56:09

US3512082

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'UN Jul 2008' reason for change: New Information	Allison Crain (b) (4)	09 Oct 2020 18:08:34
User entered 'un Dec 2019'	Taylor Johnson (b) (4)	15 Aug 2020 00:56:09

**US3512082**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:56:09

**US3512082**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:56:09

**US3512082**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:56:09

**US3512082**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:56:09

**US3512082**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jul 2008'	System	09 Oct 2020 18:08:34
User entered 'Dec 2019'	System	15 Aug 2020 00:56:09



**US3512082**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2008'	System	09 Oct 2020 18:08:34
User entered '2019'	System	15 Aug 2020 00:56:09

**US3512082**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	15 Aug 2020 00:56:09

**US3512082**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	15 Aug 2020 00:56:09

US3512082

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:00:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:45:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:45:17
Data point term sent to Coder	System	08 Oct 2020 17:49:39
User entered 'hypertension'	Brenda Anderson (b) (4)	08 Oct 2020 17:48:39

US3512082

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2008'	Brenda Anderson (b) (4)	08 Oct 2020 17:48:39

**US3512082**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Brenda Anderson (b) (4)	08 Oct 2020 17:48:39

**US3512082**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	08 Oct 2020 17:48:39

**US3512082**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Brenda Anderson (b) (4)	08 Oct 2020 17:48:39



**US3512082**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Brenda Anderson (b) (4)	08 Oct 2020 17:48:39

**US3512082**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2008'	System	08 Oct 2020 17:48:39

**US3512082**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2008'	System	08 Oct 2020 17:48:39

**US3512082**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	08 Oct 2020 17:48:39

**US3512082**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	08 Oct 2020 17:48:39

US3512082

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 08:00:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 16:13:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 16:13:23
Data point term sent to Coder	System	20 Nov 2020 13:43:38
User entered 'constipation'	Brenda Anderson (b) (4)	20 Nov 2020 13:43:15

US3512082

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 08:00:37

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'un UNK 2007'	Brenda Anderson (b) (4)	20 Nov 2020 13:43:15

**US3512082**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Brenda Anderson (b) (4)	20 Nov 2020 13:43:15



**US3512082**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 08:00:37**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	20 Nov 2020 13:43:15

**US3512082**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 08:00:37**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Brenda Anderson (b) (4)	20 Nov 2020 13:43:15

**US3512082**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Brenda Anderson (b) (4)	20 Nov 2020 13:43:15

**US3512082**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'Jan 2007'	System	20 Nov 2020 13:43:15

**US3512082**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 08:00:37**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '2007'	System	20 Nov 2020 13:43:15

**US3512082**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	20 Nov 2020 13:43:15

**US3512082**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 08:00:37**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered empty.	System	20 Nov 2020 13:43:15

US3512082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:04:54



US3512082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '14 Aug 2020'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:04:54

US3512082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '13:50'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:04:54

**US3512082**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered '14 Aug 2020 13:50'	System	15 Aug 2020 00:04:54

US3512082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '71' in	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:04:54
DataPoint set to visible.	(b) (4) System	14 Aug 2020 19:17:19

US3512082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '207' lb	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:04:54
DataPoint set to visible.	(b) (4) System	14 Aug 2020 19:17:19

US3512082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
Amendment Manager: User entered '28.93101'	System	16 Sep 2020 23:57:40
User entered '28.9'	System	15 Aug 2020 00:04:54
DataPoint set to visible.	System	14 Aug 2020 19:17:19

**US3512082**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'kg/m2'	System	15 Aug 2020 00:04:54
DataPoint set to visible.	System	14 Aug 2020 19:17:19

US3512082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered missing code ND - Not Done.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:04:54



US3512082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4)	
Query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 11:06:56
User entered empty; reason for change Data Entry Error	Allison Crain (b) (4)	24 Aug 2020 18:07:00
User opened query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4)	
User entered 'Oral (Oral)'	Allison Crain (b) (4)	24 Aug 2020 18:06:56
	(b) (4)	
	(b) (4), (b) (6)	24 Aug 2020 03:54:16
	Taylor Johnson (b) (4)	15 Aug 2020 00:04:54
	(b) (4)	

**US3512082**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:04:54

**US3512082**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered missing code ND - Not Done.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:04:54

**US3512082**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'bpm'	System	15 Aug 2020 00:04:54

US3512082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered missing code ND - Not Done.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:04:54

US3512082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'breaths/min'	System	15 Aug 2020 00:04:54

US3512082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered missing code ND - Not Done.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:04:54

**US3512082**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'mmHg'	System	15 Aug 2020 00:04:54



US3512082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered missing code ND - Not Done.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:04:54

**US3512082**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User entered 'mmHg'	System	15 Aug 2020 00:04:54

**US3512082**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42

US3512082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42

US3512082

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:05

US3512082

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Sep 2020 17:43:17
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 17:58:34
User entered '14 Aug 2020'	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:05:05

US3512082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:37

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

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Folder: Screening

Form: Risk of Exposure

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**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:29



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Folder: Screening

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**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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

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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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

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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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Taylor Johnson (b) (4)	15 Aug 2020 00:05:29



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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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

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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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

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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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

US3512082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:37

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

US3512082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:37

**Resides in Nursing Home or Assisted Living Facility**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

US3512082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:37

**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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

US3512082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:37

[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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:37

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)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:29



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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'I'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:05:29

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	28 Aug 2020 13:57:53
User entered '0'	(b) (4)	
	Taylor Johnson (b) (4)	15 Aug 2020 00:05:29
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:10:42
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'HAS ATTENDED LARGE GROUPS EVENTS IN THE PAST FEW WEEKS (WATER PARK, FAMILY GATHERING); ROUTINELY GOES TO PLACES WHERE PEOPLE GATHER (GROCERY, TARGET, HARDWARE STORE MULTIPLE TIMES A WEEK)' reason for change:	Allison Crain (b) (4)	28 Aug 2020 13:57:53
Data Entry Error	(b) (4)	
User entered empty.	Taylor Johnson (b) (4)	15 Aug 2020 00:05:29
	(b) (4)	

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	14 Aug 2020 19:17:44

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '14 Aug 2020'	Brenda Anderson (b) (4)	14 Aug 2020 19:17:44

US3512082

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:00:37

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Clinic (Clinic)'	Brenda Anderson (b) (4)	14 Aug 2020 19:17:44

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'VISIT1'	System	14 Aug 2020 19:17:44

US3512082

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:37

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:20:41



US3512082

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:37

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:37:49
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:37:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 18:20:41
User entered '186318' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:20:41

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:37

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 18:20:41

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:37

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Taylor Johnson (b) (4)	15 Aug 2020 00:06:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:37

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Taylor Johnson (b) (4)	15 Aug 2020 00:06:55

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 08:00:37**

[Severe obesity \(body mass index > or = 40kg/m2\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:06:55

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 08:00:37**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:06:55

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 08:00:37**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:06:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:37

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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 07:01:50
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'Completed' (Site from DM).	Allison Crain (b) (4)	04 Nov 2020 16:54:04
User entered 'No (N)'	(b) (4)	
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	Allison Crain (b) (4)	04 Nov 2020 16:54:01
Amendment Manager: DataPoint set to visible.	(b) (4)	
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	03 Nov 2020 14:13:33
	System	19 Sep 2020 10:21:18
	System	19 Sep 2020 07:21:36



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per CDM: ND noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Sep 2020 09:14:47
Query 'Per CDM: ND noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you.' answered with 'done' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	31 Aug 2020 20:47:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Brenda Anderson (b) (4) (b) (4)	31 Aug 2020 20:47:19
User opened query 'Per CDM: ND noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 08:41:34
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	31 Aug 2020 20:47:19
User entered missing code ND - Not Done.	(b) (4)	
	Taylor Johnson (b) (4)	15 Aug 2020 00:09:08
	(b) (4)	

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per CDM: ND noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Sep 2020 09:14:47
Query 'Per CDM: ND noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you.' answered with 'done' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	31 Aug 2020 20:47:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Brenda Anderson (b) (4) (b) (4)	31 Aug 2020 20:47:19
User opened query 'Per CDM: ND noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 08:41:34
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:09:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	31 Aug 2020 20:47:19
User entered missing code ND - Not Done.	(b) (4)	
	Taylor Johnson (b) (4)	15 Aug 2020 00:09:08
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:09:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '14 Aug 2020'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '13:50'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08



**US3512082**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered '14 Aug 2020 13:50'	System	15 Aug 2020 00:09:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '98.2' F	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (Oral)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '60'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'bpm'	System	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '16'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'breaths/min'	System	15 Aug 2020 00:09:08



US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '146'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'mmHg'	System	15 Aug 2020 00:09:08

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '84'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'mmHg'	System	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per CDM: ND noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Sep 2020 09:14:47
Query 'Per CDM: ND noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you.' answered with 'done' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	31 Aug 2020 20:47:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Brenda Anderson (b) (4) (b) (4)	31 Aug 2020 20:47:19
User opened query 'Per CDM: ND noted for HEIGHT and WEIGHT, however please also keep the Units blank for both the data-fields. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 08:41:34
User entered missing code ND - Not Done.	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Brenda Anderson (b) (4)	31 Aug 2020 20:47:19
User entered missing code ND - Not Done.	(b) (4)	
	Taylor Johnson (b) (4)	15 Aug 2020 00:09:08
	(b) (4)	

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08



US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '14 Aug 2020'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 04:37:46
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minutes post dose per protocol' (Site from System).	Taylor Johnson (b) (4)	15 Aug 2020 00:09:24
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	15 Aug 2020 00:09:08
User entered '15:38'	Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered '14 Aug 2020 15:38'	System	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '97.5' F	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (Oral)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '58'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'bpm'	System	15 Aug 2020 00:09:08



US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '15'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'breaths/min'	System	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '149'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'mmHg'	System	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '81'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'mmHg'	System	15 Aug 2020 00:09:08

US3512082

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Brenda Anderson (b) (4)	14 Aug 2020 19:19:18

US3512082

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:37

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Brenda Anderson (b) (4)	14 Aug 2020 19:19:18



**US3512082**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	14 Aug 2020 19:18:46

US3512082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Brenda Anderson (b) (4)	14 Aug 2020 19:18:46

US3512082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Brenda Anderson (b) (4)	14 Aug 2020 19:18:46

US3512082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 19:18:46

US3512082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '14 Aug 2020'	Brenda Anderson (b) (4)	14 Aug 2020 19:18:46

US3512082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '15:08'	Brenda Anderson (b) (4)	14 Aug 2020 19:18:46

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered '14 Aug 2020 15:08'	System	14 Aug 2020 19:18:46

US3512082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Left Arm (LEFT ARM)'	Brenda Anderson (b) (4)	14 Aug 2020 19:18:46



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'ONCE'	System	14 Aug 2020 19:18:46

US3512082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 19:18:46

US3512082

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:10:19

US3512082

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '14 Aug 2020'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:10:19

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '14:30'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:10:19

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered '14 Aug 2020 14:30'	System	15 Aug 2020 00:10:19

US3512082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:00:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '14 Aug 2020'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:10:37

US3512082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:00:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:10:37



**US3512082**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:10:37

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '14:18'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:10:37

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered '14 Aug 2020 14:18'	System	15 Aug 2020 00:10:37

US3512082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:00:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:10:37

US3512082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:00:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:10:37

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:00:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:10:37

**US3512082**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered empty.	System	15 Aug 2020 00:10:37

US3512082

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:00:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:10:42



**US3512082**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered '1'	System	15 Aug 2020 00:10:42

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:34:20', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd35906ca-7c6f-4f5a-ae44-3c622c9c8438' User entered 'Yes (Y)'	System	14 Aug 2020 19:35:06
	System	14 Aug 2020 19:35:06

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:34:38', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd35906ca-7c6f-4f5a-ae44-3c622c9c8438' User entered '97.5'	System	14 Aug 2020 19:35:06
	System	14 Aug 2020 19:35:06

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:34:47', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd35906ca-7c6f-4f5a-ae44-3c622c9c8438'	System	14 Aug 2020 19:35:06
User entered 'No (N)'	System	14 Aug 2020 19:35:06

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:35:03', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd35906ca-7c6f-4f5a-ae44-3c622c9c8438'	System	14 Aug 2020 19:35:06
User entered '14 Aug 2020 15:35'	System	14 Aug 2020 19:35:06

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Aug 2020 15:28'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Aug 2020 17:58'	System	14 Aug 2020 19:18:46



US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:05:13', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e48a63cc-ae9c-4e94-9a68-ee943cd47195' User entered 'Yes (Y)'	System	14 Aug 2020 23:05:47
	System	14 Aug 2020 23:05:47

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:05:26', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e48a63cc-ae9c-4e94-9a68-ee943cd47195' User entered '97.5'	System	14 Aug 2020 23:05:47
	System	14 Aug 2020 23:05:47

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:05:31', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e48a63cc-ae9c-4e94-9a68-ee943cd47195'	System	14 Aug 2020 23:05:47
User entered 'No (N)'	System	14 Aug 2020 23:05:47

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:05:43', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e48a63cc-ae9c-4e94-9a68-ee943cd47195'	System	14 Aug 2020 23:05:47
User entered '14 Aug 2020 19:05'	System	14 Aug 2020 23:05:47

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Aug 2020 18:53'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 2'	System	14 Aug 2020 19:18:46



US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:57:18', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1c19f0da-c6c2-488f-a604-e46e632d4f07'	System	15 Aug 2020 22:57:53
User entered 'Yes (Y)'	System	15 Aug 2020 22:57:53

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:57:32', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1c19f0da-c6c2-488f-a604-e46e632d4f07' User entered '96.7'	System	15 Aug 2020 22:57:53
	System	15 Aug 2020 22:57:53

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:57:38', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1c19f0da-c6c2-488f-a604-e46e632d4f07'	System	15 Aug 2020 22:57:53
User entered 'No (N)'	System	15 Aug 2020 22:57:53

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:57:50', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1c19f0da-c6c2-488f-a604-e46e632d4f07'	System	15 Aug 2020 22:57:53
User entered '15 Aug 2020 18:57'	System	15 Aug 2020 22:57:53

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 3'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:34:26', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'a5e3dec2-401c-488c-8c1a-5fd71a242897' User entered 'Yes (Y)'	System	16 Aug 2020 22:34:55
	System	16 Aug 2020 22:34:55



US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:34:41', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'a5e3dec2-401c-488c-8c1a-5fd71a242897' User entered '96.8'	System	16 Aug 2020 22:34:55
	System	16 Aug 2020 22:34:55

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:34:45', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'a5e3dec2-401c-488c-8c1a-5fd71a242897'	System	16 Aug 2020 22:34:55
User entered 'No (N)'	System	16 Aug 2020 22:34:55

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:34:54', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'a5e3dec2-401c-488c-8c1a-5fd71a242897' User entered '16 Aug 2020 18:34'	System	16 Aug 2020 22:34:55
	System	16 Aug 2020 22:34:55

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 4'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:32:27', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '3d2c3212-3c18-4044-bfe6-2510685e883e' User entered 'Yes (Y)'	System	17 Aug 2020 22:32:53
	System	17 Aug 2020 22:32:53

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:32:38', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '3d2c3212-3c18-4044-bfe6-2510685e883e' User entered '95.9'	System	17 Aug 2020 22:32:53
	System	17 Aug 2020 22:32:53



US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:32:42', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '3d2c3212-3c18-4044-bfe6-2510685e883e' User entered 'No (N)'	System	17 Aug 2020 22:32:53
	System	17 Aug 2020 22:32:53

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:32:50', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '3d2c3212-3c18-4044-bfe6-2510685e883e' User entered '17 Aug 2020 18:32'	System	17 Aug 2020 22:32:53
	System	17 Aug 2020 22:32:53

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 5'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:25:09', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f2ee39f4-468b-4e12-909f-bf101cd5ef54' User entered 'Yes (Y)'	System	18 Aug 2020 22:25:41
	System	18 Aug 2020 22:25:41

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:25:19', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f2ee39f4-468b-4e12-909f-bf101cd5ef54' User entered '97.4'	System	18 Aug 2020 22:25:41
	System	18 Aug 2020 22:25:41

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:25:25', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f2ee39f4-468b-4e12-909f-bf101cd5ef54'	System	18 Aug 2020 22:25:41
User entered 'No (N)'	System	18 Aug 2020 22:25:41



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:25:38', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f2ee39f4-468b-4e12-909f-bf101cd5ef54'	System	18 Aug 2020 22:25:41
User entered '18 Aug 2020 18:25'	System	18 Aug 2020 22:25:41

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 6'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:21:38', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '03e21138-d0c7-461c-b365-83b1200469a9' User entered 'Yes (Y)'	System	19 Aug 2020 23:22:18
	System	19 Aug 2020 23:22:18

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:21:48', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '03e21138-d0c7-461c-b365-83b1200469a9' User entered '96.8'	System	19 Aug 2020 23:22:18
	System	19 Aug 2020 23:22:18

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:21:54', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '03e21138-d0c7-461c-b365-83b1200469a9'	System	19 Aug 2020 23:22:18
User entered 'No (N)'	System	19 Aug 2020 23:22:18

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:22:14', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '03e21138-d0c7-461c-b365-83b1200469a9' User entered '19 Aug 2020 19:22'	System	19 Aug 2020 23:22:18
	System	19 Aug 2020 23:22:18



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 7'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:54:21', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'a06c8bf4-dd6e-4b2d-a463-b618e0d22a08' User entered 'Yes (Y)'	System	20 Aug 2020 21:54:48
	System	20 Aug 2020 21:54:48

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:54:32', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'a06c8bf4-dd6e-4b2d-a463-b618e0d22a08' User entered '96.5'	System	20 Aug 2020 21:54:48
	System	20 Aug 2020 21:54:48

US3512082

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:54:36', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'a06c8bf4-dd6e-4b2d-a463-b618e0d22a08'	System	20 Aug 2020 21:54:48
User entered 'No (N)'	System	20 Aug 2020 21:54:48

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:54:45', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'a06c8bf4-dd6e-4b2d-a463-b618e0d22a08' User entered '20 Aug 2020 17:54'	System	20 Aug 2020 21:54:48
	System	20 Aug 2020 21:54:48

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 19:18:46



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:36:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'dcbcb8e0-737e-46ea-b4f1-ac040909c664' User entered 'None (1)'	System	14 Aug 2020 19:36:48
	System	14 Aug 2020 19:36:48

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:36:12', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'dcbcb8e0-737e-46ea-b4f1-ac040909c664' User entered 'No (N)'	System	14 Aug 2020 19:36:48
	System	14 Aug 2020 19:36:48

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:36:17', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'dcbcb8e0-737e-46ea-b4f1-ac040909c664' User entered 'No (N)'	System	14 Aug 2020 19:36:48
	System	14 Aug 2020 19:36:48

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:36:25', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'dcbcb8e0-737e-46ea-b4f1-ac040909c664' User entered 'None (1)'	System	14 Aug 2020 19:36:48
	System	14 Aug 2020 19:36:48

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:36:43', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'dcbcb8e0-737e-46ea-b4f1-ac040909c664' User entered '14 Aug 2020 15:36'	System	14 Aug 2020 19:36:48
	System	14 Aug 2020 19:36:48

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Aug 2020 15:28'	System	14 Aug 2020 19:18:46



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Aug 2020 17:58'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:06:17', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '87a6123a-7c90-4d36-b0ac-2a9e1ed82e80' User entered 'None (1)'	System	14 Aug 2020 23:07:04
	System	14 Aug 2020 23:07:04

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:06:22', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '87a6123a-7c90-4d36-b0ac-2a9e1ed82e80' User entered 'No (N)'	System	14 Aug 2020 23:07:04
	System	14 Aug 2020 23:07:04

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:06:27', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '87a6123a-7c90-4d36-b0ac-2a9e1ed82e80' User entered 'No (N)'	System	14 Aug 2020 23:07:04
	System	14 Aug 2020 23:07:04

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:06:44', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '87a6123a-7c90-4d36-b0ac-2a9e1ed82e80' User entered 'None (1)'	System	14 Aug 2020 23:07:04
	System	14 Aug 2020 23:07:04

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:07:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '87a6123a-7c90-4d36-b0ac-2a9e1ed82e80' User entered '14 Aug 2020 19:07'	System	14 Aug 2020 23:07:04
	System	14 Aug 2020 23:07:04

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Aug 2020 18:53'	System	14 Aug 2020 19:18:46



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 2'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:58:05', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '27654ae6-e6da-4526-9b09-bc259aafaa3e' User entered 'None (1)'	System	15 Aug 2020 22:58:52
	System	15 Aug 2020 22:58:52

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:58:16', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '27654ae6-e6da-4526-9b09-bc259aafaa3e' User entered 'No (N)'	System	15 Aug 2020 22:58:52
	System	15 Aug 2020 22:58:52

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:58:21', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '27654ae6-e6da-4526-9b09-bc259aafaa3e' User entered 'No (N)'	System	15 Aug 2020 22:58:52
	System	15 Aug 2020 22:58:52

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:58:35', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '27654ae6-e6da-4526-9b09-bc259aafaa3e' User entered 'None (1)'	System	15 Aug 2020 22:58:52
	System	15 Aug 2020 22:58:52

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:58:49', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '27654ae6-e6da-4526-9b09-bc259aafaa3e' User entered '15 Aug 2020 18:58'	System	15 Aug 2020 22:58:52
	System	15 Aug 2020 22:58:52

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 19:18:46



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 3'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:35:03', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd6b5b8b8-bbdd-487d-8eed-f2955dc1a272'	System	16 Aug 2020 22:35:45
User entered 'None (1)'	System	16 Aug 2020 22:35:45

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:35:09', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd6b5b8b8-bbdd-487d-8eed-f2955dc1a272'	System	16 Aug 2020 22:35:45
User entered 'No (N)'	System	16 Aug 2020 22:35:45

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:35:22', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd6b5b8b8-bbdd-487d-8eed-f2955dc1a272'	System	16 Aug 2020 22:35:45
User entered 'No (N)'	System	16 Aug 2020 22:35:45

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:35:29', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd6b5b8b8-bbdd-487d-8eed-f2955dc1a272'	System	16 Aug 2020 22:35:45
User entered 'None (1)'	System	16 Aug 2020 22:35:45

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:35:44', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd6b5b8b8-bbdd-487d-8eed-f2955dc1a272'	System	16 Aug 2020 22:35:45
User entered '16 Aug 2020 18:35'	System	16 Aug 2020 22:35:45

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:18:46



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 4'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:33:06', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '80a2dcf9-9725-4b7d-b898-a76ef3c084ce' User entered 'None (1)'	System	17 Aug 2020 22:34:01
	System	17 Aug 2020 22:34:01

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:33:15', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '80a2dcf9-9725-4b7d-b898-a76ef3c084ce' User entered 'No (N)'	System	17 Aug 2020 22:34:01
	System	17 Aug 2020 22:34:01

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:33:20', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '80a2dcf9-9725-4b7d-b898-a76ef3c084ce' User entered 'No (N)'	System	17 Aug 2020 22:34:01
	System	17 Aug 2020 22:34:01

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:33:33', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '80a2dcf9-9725-4b7d-b898-a76ef3c084ce' User entered 'None (1)'	System	17 Aug 2020 22:34:01
	System	17 Aug 2020 22:34:01

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:33:59', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '80a2dcf9-9725-4b7d-b898-a76ef3c084ce' User entered '17 Aug 2020 18:33'	System	17 Aug 2020 22:34:01
	System	17 Aug 2020 22:34:01

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 19:18:46



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 5'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:26:01', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e34bd3c7-9d0f-47b4-bb89-1e1d7a28040e' User entered 'None (1)'	System	18 Aug 2020 22:26:42
	System	18 Aug 2020 22:26:42

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:26:10', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e34bd3c7-9d0f-47b4-bb89-1e1d7a28040e' User entered 'No (N)'	System	18 Aug 2020 22:26:42
	System	18 Aug 2020 22:26:42

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:26:19', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e34bd3c7-9d0f-47b4-bb89-1e1d7a28040e' User entered 'No (N)'	System	18 Aug 2020 22:26:42
	System	18 Aug 2020 22:26:42

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:26:28', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e34bd3c7-9d0f-47b4-bb89-1e1d7a28040e' User entered 'None (1)'	System	18 Aug 2020 22:26:42
	System	18 Aug 2020 22:26:42

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:26:38', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e34bd3c7-9d0f-47b4-bb89-1e1d7a28040e' User entered '18 Aug 2020 18:26'	System	18 Aug 2020 22:26:42
	System	18 Aug 2020 22:26:42

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 19:18:46



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 6'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:22:27', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '8fc66650-fb0d-4468-a810-546f210050fc' User entered 'None (1)'	System	19 Aug 2020 23:23:04
	System	19 Aug 2020 23:23:04

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:22:36', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '8fc66650-fb0d-4468-a810-546f210050fc' User entered 'No (N)'	System	19 Aug 2020 23:23:04
	System	19 Aug 2020 23:23:04

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:22:41', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '8fc66650-fb0d-4468-a810-546f210050fc' User entered 'No (N)'	System	19 Aug 2020 23:23:04
	System	19 Aug 2020 23:23:04

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:22:50', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '8fc66650-fb0d-4468-a810-546f210050fc' User entered 'None (1)'	System	19 Aug 2020 23:23:04
	System	19 Aug 2020 23:23:04

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:23:02', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '8fc66650-fb0d-4468-a810-546f210050fc' User entered '19 Aug 2020 19:23'	System	19 Aug 2020 23:23:04
	System	19 Aug 2020 23:23:04

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 19:18:46



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 7'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:54:55', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f316fb7b-6e04-4f10-90fd-8f2bd40cfc89'	System	20 Aug 2020 21:55:43
User entered 'None (1)'	System	20 Aug 2020 21:55:43

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:55:05', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f316fb7b-6e04-4f10-90fd-8f2bd40cfc89'	System	20 Aug 2020 21:55:43
User entered 'No (N)'	System	20 Aug 2020 21:55:43

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:55:17', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f316fb7b-6e04-4f10-90fd-8f2bd40cfc89'	System	20 Aug 2020 21:55:43
User entered 'No (N)'	System	20 Aug 2020 21:55:43

US3512082

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:55:26', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f316fb7b-6e04-4f10-90fd-8f2bd40cfc89'	System	20 Aug 2020 21:55:43
User entered 'None (1)'	System	20 Aug 2020 21:55:43

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:55:42', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f316fb7b-6e04-4f10-90fd-8f2bd40cfc89' User entered '20 Aug 2020 17:55'	System	20 Aug 2020 21:55:43
	System	20 Aug 2020 21:55:43

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 19:18:46



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:36:56', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '0002d223-9bae-4d98-aa4c-b27c15229eb8' User entered 'None (0)'	System	14 Aug 2020 19:38:02
	System	14 Aug 2020 19:38:02

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:37:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '0002d223-9bae-4d98-aa4c-b27c15229eb8' User entered 'None (0)'	System	14 Aug 2020 19:38:02
	System	14 Aug 2020 19:38:02

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:37:04', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '0002d223-9bae-4d98-aa4c-b27c15229eb8' User entered 'None (0)'	System	14 Aug 2020 19:38:02
	System	14 Aug 2020 19:38:02

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:37:09', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '0002d223-9bae-4d98-aa4c-b27c15229eb8' User entered 'None (0)'	System	14 Aug 2020 19:38:02
	System	14 Aug 2020 19:38:02

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:37:13', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '0002d223-9bae-4d98-aa4c-b27c15229eb8' User entered 'None (0)'	System	14 Aug 2020 19:38:02
	System	14 Aug 2020 19:38:02

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:37:18', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '0002d223-9bae-4d98-aa4c-b27c15229eb8' User entered 'None (0)'	System	14 Aug 2020 19:38:02
	System	14 Aug 2020 19:38:02



US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:37:27', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '0002d223-9bae-4d98-aa4c-b27c15229eb8' User entered 'No (N)'	System	14 Aug 2020 19:38:02
	System	14 Aug 2020 19:38:02

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T15:37:53', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '0002d223-9bae-4d98-aa4c-b27c15229eb8' User entered '14 Aug 2020 15:37'	System	14 Aug 2020 19:38:02
	System	14 Aug 2020 19:38:02

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Aug 2020 15:28'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Aug 2020 17:58'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:07:12', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '592c48c5-fecf-4cae-bdf6-44f81683208a' User entered 'None (0)'	System	14 Aug 2020 23:08:08
	System	14 Aug 2020 23:08:08

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:07:17', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '592c48c5-fecf-4cae-bdf6-44f81683208a' User entered 'None (0)'	System	14 Aug 2020 23:08:08
	System	14 Aug 2020 23:08:08

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:07:21', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '592c48c5-fecf-4cae-bdf6-44f81683208a' User entered 'None (0)'	System	14 Aug 2020 23:08:08
	System	14 Aug 2020 23:08:08



US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:07:26', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '592c48c5-fecf-4cae-bdf6-44f81683208a' User entered 'None (0)'	System	14 Aug 2020 23:08:08
	System	14 Aug 2020 23:08:08

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:07:32', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '592c48c5-fecf-4cae-bdf6-44f81683208a' User entered 'None (0)'	System	14 Aug 2020 23:08:08
	System	14 Aug 2020 23:08:08

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:07:42', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '592c48c5-fecf-4cae-bdf6-44f81683208a' User entered 'None (0)'	System	14 Aug 2020 23:08:08
	System	14 Aug 2020 23:08:08

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:07:49', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '592c48c5-fecf-4cae-bdf6-44f81683208a' User entered 'No (N)'	System	14 Aug 2020 23:08:08
	System	14 Aug 2020 23:08:08

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-14T19:08:06', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '592c48c5-fecf-4cae-bdf6-44f81683208a' User entered '14 Aug 2020 19:08'	System	14 Aug 2020 23:08:08
	System	14 Aug 2020 23:08:08

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Aug 2020 18:53'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 2'	System	14 Aug 2020 19:18:46



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:58:56', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1d58bdb2-04d7-46e5-9a4d-9eb090aa07f1' User entered 'None (0)'	System	15 Aug 2020 22:59:48
	System	15 Aug 2020 22:59:48

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:59:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1d58bdb2-04d7-46e5-9a4d-9eb090aa07f1' User entered 'None (0)'	System	15 Aug 2020 22:59:48
	System	15 Aug 2020 22:59:48

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:59:03', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1d58bdb2-04d7-46e5-9a4d-9eb090aa07f1' User entered 'None (0)'	System	15 Aug 2020 22:59:48
	System	15 Aug 2020 22:59:48

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:59:08', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1d58bdb2-04d7-46e5-9a4d-9eb090aa07f1' User entered 'None (0)'	System	15 Aug 2020 22:59:48
	System	15 Aug 2020 22:59:48

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:59:13', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1d58bdb2-04d7-46e5-9a4d-9eb090aa07f1' User entered 'None (0)'	System	15 Aug 2020 22:59:48
	System	15 Aug 2020 22:59:48

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:59:16', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1d58bdb2-04d7-46e5-9a4d-9eb090aa07f1' User entered 'None (0)'	System	15 Aug 2020 22:59:48
	System	15 Aug 2020 22:59:48

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:59:23', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1d58bdb2-04d7-46e5-9a4d-9eb090aa07f1' User entered 'No (N)'	System	15 Aug 2020 22:59:48
	System	15 Aug 2020 22:59:48

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-15T18:59:44', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1d58bdb2-04d7-46e5-9a4d-9eb090aa07f1' User entered '15 Aug 2020 18:59'	System	15 Aug 2020 22:59:48
	System	15 Aug 2020 22:59:48



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 3'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:35:51', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd98fd1b5-1d0b-449b-b6a0-54f88b3d0b6c' User entered 'None (0)'	System	16 Aug 2020 22:37:23
	System	16 Aug 2020 22:37:23

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:35:55', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd98fd1b5-1d0b-449b-b6a0-54f88b3d0b6c' User entered 'None (0)'	System	16 Aug 2020 22:37:23
	System	16 Aug 2020 22:37:23

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:35:58', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd98fd1b5-1d0b-449b-b6a0-54f88b3d0b6c' User entered 'None (0)'	System	16 Aug 2020 22:37:23
	System	16 Aug 2020 22:37:23

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:36:02', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd98fd1b5-1d0b-449b-b6a0-54f88b3d0b6c' User entered 'None (0)'	System	16 Aug 2020 22:37:23
	System	16 Aug 2020 22:37:23

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:36:05', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd98fd1b5-1d0b-449b-b6a0-54f88b3d0b6c' User entered 'None (0)'	System	16 Aug 2020 22:37:23
	System	16 Aug 2020 22:37:23



US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:36:07', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd98fd1b5-1d0b-449b-b6a0-54f88b3d0b6c' User entered 'None (0)'	System	16 Aug 2020 22:37:23
	System	16 Aug 2020 22:37:23

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:36:17', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd98fd1b5-1d0b-449b-b6a0-54f88b3d0b6c' User entered 'No (N)'	System	16 Aug 2020 22:37:23
	System	16 Aug 2020 22:37:23

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-16T18:37:21', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd98fd1b5-1d0b-449b-b6a0-54f88b3d0b6c' User entered '16 Aug 2020 18:37'	System	16 Aug 2020 22:37:23
	System	16 Aug 2020 22:37:23

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 4'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:34:07', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'eeeb24af-c846-4e46-9fcd-f0668a097dd3' User entered 'None (0)'	System	17 Aug 2020 22:35:27
	System	17 Aug 2020 22:35:27

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:34:10', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'eeeb24af-c846-4e46-9fcd-f0668a097dd3' User entered 'None (0)'	System	17 Aug 2020 22:35:27
	System	17 Aug 2020 22:35:27



US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:34:13', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'eeeb24af-c846-4e46-9fcd-f0668a097dd3' User entered 'None (0)'	System	17 Aug 2020 22:35:27
	System	17 Aug 2020 22:35:27

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:34:17', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'eeeb24af-c846-4e46-9fcd-f0668a097dd3' User entered 'None (0)'	System	17 Aug 2020 22:35:27
	System	17 Aug 2020 22:35:27

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:34:21', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'eeeb24af-c846-4e46-9fcd-f0668a097dd3' User entered 'None (0)'	System	17 Aug 2020 22:35:27
	System	17 Aug 2020 22:35:27

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:34:37', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'eeeb24af-c846-4e46-9fcd-f0668a097dd3' User entered 'None (0)'	System	17 Aug 2020 22:35:27
	System	17 Aug 2020 22:35:27

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:34:44', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'eeeb24af-c846-4e46-9fcd-f0668a097dd3' User entered 'No (N)'	System	17 Aug 2020 22:35:27
	System	17 Aug 2020 22:35:27

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-17T18:35:24', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'eeeb24af-c846-4e46-9fcd-f0668a097dd3' User entered '17 Aug 2020 18:35'	System	17 Aug 2020 22:35:27
	System	17 Aug 2020 22:35:27

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 19:18:46



US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 5'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:26:45', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21bdd2ef-8dad-456c-9e13-cc75b6860a46' User entered 'None (0)'	System	18 Aug 2020 22:27:36
	System	18 Aug 2020 22:27:36

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:26:49', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21bdd2ef-8dad-456c-9e13-cc75b6860a46' User entered 'None (0)'	System	18 Aug 2020 22:27:36
	System	18 Aug 2020 22:27:36

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:26:54', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21bdd2ef-8dad-456c-9e13-cc75b6860a46' User entered 'None (0)'	System	18 Aug 2020 22:27:36
	System	18 Aug 2020 22:27:36

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:27:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21bdd2ef-8dad-456c-9e13-cc75b6860a46' User entered 'None (0)'	System	18 Aug 2020 22:27:36
	System	18 Aug 2020 22:27:36

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:27:04', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21bdd2ef-8dad-456c-9e13-cc75b6860a46' User entered 'None (0)'	System	18 Aug 2020 22:27:36
	System	18 Aug 2020 22:27:36

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:27:07', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21bdd2ef-8dad-456c-9e13-cc75b6860a46' User entered 'None (0)'	System	18 Aug 2020 22:27:36
	System	18 Aug 2020 22:27:36

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:27:16', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21bdd2ef-8dad-456c-9e13-cc75b6860a46' User entered 'No (N)'	System	18 Aug 2020 22:27:36
	System	18 Aug 2020 22:27:36



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-18T18:27:32', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21bdd2ef-8dad-456c-9e13-cc75b6860a46' User entered '18 Aug 2020 18:27'	System	18 Aug 2020 22:27:36
	System	18 Aug 2020 22:27:36

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 6'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:23:12', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd3694bd3-15b2-43f2-a5ae-413b2f0aec00' User entered 'None (0)'	System	19 Aug 2020 23:24:14
	System	19 Aug 2020 23:24:14

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:23:17', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd3694bd3-15b2-43f2-a5ae-413b2f0aec00' User entered 'None (0)'	System	19 Aug 2020 23:24:14
	System	19 Aug 2020 23:24:14

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:23:23', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd3694bd3-15b2-43f2-a5ae-413b2f0aec00' User entered 'None (0)'	System	19 Aug 2020 23:24:14
	System	19 Aug 2020 23:24:14

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:23:29', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd3694bd3-15b2-43f2-a5ae-413b2f0aec00' User entered 'None (0)'	System	19 Aug 2020 23:24:14
	System	19 Aug 2020 23:24:14



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:23:35', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd3694bd3-15b2-43f2-a5ae-413b2f0aec00' User entered 'None (0)'	System	19 Aug 2020 23:24:14
	System	19 Aug 2020 23:24:14

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:23:40', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd3694bd3-15b2-43f2-a5ae-413b2f0aec00' User entered 'None (0)'	System	19 Aug 2020 23:24:14
	System	19 Aug 2020 23:24:14

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:23:49', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd3694bd3-15b2-43f2-a5ae-413b2f0aec00' User entered 'No (N)'	System	19 Aug 2020 23:24:14
	System	19 Aug 2020 23:24:14

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-19T19:24:11', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd3694bd3-15b2-43f2-a5ae-413b2f0aec00' User entered '19 Aug 2020 19:24'	System	19 Aug 2020 23:24:14
	System	19 Aug 2020 23:24:14

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 7'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:55:50', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5c571587-3f18-488d-9a7a-afc2381058c9' User entered 'None (0)'	System	20 Aug 2020 21:56:58
	System	20 Aug 2020 21:56:58



US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:55:54', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5c571587-3f18-488d-9a7a-afc2381058c9' User entered 'None (0)'	System	20 Aug 2020 21:56:58
	System	20 Aug 2020 21:56:58

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:55:57', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5c571587-3f18-488d-9a7a-afc2381058c9' User entered 'None (0)'	System	20 Aug 2020 21:56:58
	System	20 Aug 2020 21:56:58

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:56:16', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5c571587-3f18-488d-9a7a-afc2381058c9' User entered 'None (0)'	System	20 Aug 2020 21:56:58
	System	20 Aug 2020 21:56:58

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:56:22', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5c571587-3f18-488d-9a7a-afc2381058c9' User entered 'None (0)'	System	20 Aug 2020 21:56:58
	System	20 Aug 2020 21:56:58

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:56:26', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5c571587-3f18-488d-9a7a-afc2381058c9' User entered 'None (0)'	System	20 Aug 2020 21:56:58
	System	20 Aug 2020 21:56:58

US3512082

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:56:37', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5c571587-3f18-488d-9a7a-afc2381058c9' User entered 'No (N)'	System	20 Aug 2020 21:56:58
	System	20 Aug 2020 21:56:58

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-08-20T17:56:56', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5c571587-3f18-488d-9a7a-afc2381058c9' User entered '20 Aug 2020 17:56'	System	20 Aug 2020 21:56:58
	System	20 Aug 2020 21:56:58

**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 19:18:46



**US3512082**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	21 Aug 2020 13:55:08

**US3512082**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '21 Aug 2020'	(b) (4) Sheldon Warren (b) (4)	21 Aug 2020 13:55:08

US3512082

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	21 Aug 2020 13:55:08

**US3512082**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	21 Aug 2020 13:55:08

**US3512082**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	21 Aug 2020 13:55:13

**US3512082**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'I'	System	21 Aug 2020 13:55:13

**US3512082**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	28 Aug 2020 15:10:23



**US3512082**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '28 Aug 2020'	(b) (4) Sheldon Warren (b) (4)	28 Aug 2020 15:10:23

US3512082

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	28 Aug 2020 15:10:23

US3512082

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	28 Aug 2020 15:10:23

**US3512082**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	28 Aug 2020 15:10:28

**US3512082**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'I'	System	28 Aug 2020 15:10:28

**US3512082**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:58:06

US3512082

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	11 Sep 2020 17:58:15
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	11 Sep 2020 17:58:15
answered by data change (Site from System).		
User entered '04 Sep 2020' reason for change: Data Entry Error	Taylor Johnson (b) (4)	11 Sep 2020 17:58:15
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	11 Sep 2020 17:58:06
User entered '11 Sep 2020'	System	11 Sep 2020 17:58:06
	Taylor Johnson (b) (4)	11 Sep 2020 17:58:06
	(b) (4)	

US3512082

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:58:06



US3512082

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:58:06

**US3512082**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:58:21

**US3512082**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'I'	System	11 Sep 2020 17:58:21

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:58:34

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '11 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:58:34

US3512082

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:37

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Clinic (Clinic)'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:58:34

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'VISIT2'	System	11 Sep 2020 17:58:34

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17



US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '11 Sep 2020'	(b) (4) Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '13:00'	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered '11 Sep 2020 13:00'	System	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '97.6' F	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (Oral)'	(b) (4) Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '56'	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17



**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'bpm'	System	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '12'	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'breaths/min'	System	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '139'	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'mmHg'	System	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '76'	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'mmHg'	System	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17



US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '11 Sep 2020'	(b) (4) Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Sep 2020 18:49:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	11 Sep 2020 18:49:54
User entered '14:20' reason for change: Data Entry Error	Brenda Anderson (b) (4)	11 Sep 2020 18:49:54
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Sep 2020 18:49:17
User entered empty.	System	11 Sep 2020 18:49:17
	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17
	(b) (4)	

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered '11 Sep 2020 14:20'	System	11 Sep 2020 18:49:54
User entered empty.	System	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '97.6' F	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (Oral)'	(b) (4) Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '57'	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17



**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'bpm'	System	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '14'	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'breaths/min'	System	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '142'	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'mmHg'	System	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '77'	Brenda Anderson (b) (4)	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'mmHg'	System	11 Sep 2020 18:49:17

US3512082

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:58:57



US3512082

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '11 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:58:57

US3512082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:59:21

US3512082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:59:21

US3512082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Taylor Johnson (b) (4)	11 Sep 2020 17:59:21

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 17:59:21

US3512082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '11 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:59:21

US3512082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '13:49'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:59:21

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered '11 Sep 2020 13:49'	System	11 Sep 2020 17:59:21



US3512082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Left Arm (LEFT ARM)'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:59:21

US3512082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'ONCE'	System	11 Sep 2020 17:59:21

US3512082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 17:59:21

US3512082

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:59:39

US3512082

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '11 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:59:39

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '13:25'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:59:39

US3512082

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered '11 Sep 2020 13:25'	System	11 Sep 2020 17:59:39

US3512082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:00:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '11 Sep 2020'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:59:55



**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Johnson (b) (4) (b) (4)	11 Sep 2020 17:59:55

US3512082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:00:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:59:55

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:00:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '13:16'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:59:55

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered '11 Sep 2020 13:16'	System	11 Sep 2020 17:59:55

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Johnson (b) (4) (b) (4)	11 Sep 2020 17:59:55

US3512082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:00:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:59:55

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:00:37**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 17:59:55

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered empty.	System	11 Sep 2020 17:59:55



US3512082

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	11 Sep 2020 18:00:12

**US3512082**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'I'	System	11 Sep 2020 18:00:12

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:24:18', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'afb118d9-4af6-41e6-b6b2-f31b8526225d' User entered 'Yes (Y)'	System	11 Sep 2020 18:24:53
	System	11 Sep 2020 18:24:53

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:24:32', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'afb118d9-4af6-41e6-b6b2-f31b8526225d' User entered '97.9'	System	11 Sep 2020 18:24:53
	System	11 Sep 2020 18:24:53

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:24:37', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'afb118d9-4af6-41e6-b6b2-f31b8526225d' User entered 'No (N)'	System	11 Sep 2020 18:24:53
	System	11 Sep 2020 18:24:53

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:24:46', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'afb118d9-4af6-41e6-b6b2-f31b8526225d' User entered '11 Sep 2020 14:24'	System	11 Sep 2020 18:24:53
	System	11 Sep 2020 18:24:53

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '11 Sep 2020 14:09'	System	11 Sep 2020 17:59:21



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '11 Sep 2020 16:39'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:30:45', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f0bbfd80-644a-4945-8b8b-8d91245c0171' User entered 'Yes (Y)'	System	11 Sep 2020 22:31:31
	System	11 Sep 2020 22:31:31

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:31:02', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f0bbfd80-644a-4945-8b8b-8d91245c0171' User entered '96.5'	System	11 Sep 2020 22:31:31
	System	11 Sep 2020 22:31:31

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:31:10', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f0bbfd80-644a-4945-8b8b-8d91245c0171' User entered 'No (N)'	System	11 Sep 2020 22:31:31
	System	11 Sep 2020 22:31:31

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:31:24', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f0bbfd80-644a-4945-8b8b-8d91245c0171' User entered '11 Sep 2020 18:31'	System	11 Sep 2020 22:31:31
	System	11 Sep 2020 22:31:31

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '11 Sep 2020 17:34'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:59:21



US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 2'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:24:30', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '3f0a3977-1203-4674-ae88-7fafd9ba959c' User entered 'Yes (Y)'	System	12 Sep 2020 22:25:00
	System	12 Sep 2020 22:25:00

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:24:43', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '3f0a3977-1203-4674-ae88-7fafd9ba959c' User entered '95.9'	System	12 Sep 2020 22:25:00
	System	12 Sep 2020 22:25:00

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:24:50', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '3f0a3977-1203-4674-ae88-7fafd9ba959c'	System	12 Sep 2020 22:25:00
User entered 'No (N)'	System	12 Sep 2020 22:25:00

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:24:59', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '3f0a3977-1203-4674-ae88-7fafd9ba959c' User entered '12 Sep 2020 18:24'	System	12 Sep 2020 22:25:00
	System	12 Sep 2020 22:25:00

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 08:00:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 3'	System	11 Sep 2020 17:59:21



US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:18:03', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'bfe7f914-909f-42da-b668-8dd8eeaf3f9f' User entered 'Yes (Y)'	System	13 Sep 2020 22:18:30
	System	13 Sep 2020 22:18:30

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:18:11', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'bfe7f914-909f-42da-b668-8dd8eeaf3f9f' User entered '96.3'	System	13 Sep 2020 22:18:30
	System	13 Sep 2020 22:18:30

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:18:17', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'bfe7f914-909f-42da-b668-8dd8eeaf3f9f' User entered 'No (N)'	System	13 Sep 2020 22:18:30
	System	13 Sep 2020 22:18:30

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:18:27', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'bfe7f914-909f-42da-b668-8dd8eeaf3f9f' User entered '13 Sep 2020 18:18'	System	13 Sep 2020 22:18:30
	System	13 Sep 2020 22:18:30

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 4'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:45:15', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c88cd263-948f-448b-88ac-efa5ea52d153'	System	14 Sep 2020 21:45:42
User entered 'Yes (Y)'	System	14 Sep 2020 21:45:42



US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:45:25', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c88cd263-948f-448b-88ac-efa5ea52d153'	System	14 Sep 2020 21:45:42
User entered '96.9'	System	14 Sep 2020 21:45:42

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:45:30', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c88cd263-948f-448b-88ac-efa5ea52d153'	System	14 Sep 2020 21:45:42
User entered 'No (N)'	System	14 Sep 2020 21:45:42

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:45:39', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c88cd263-948f-448b-88ac-efa5ea52d153'	System	14 Sep 2020 21:45:42
User entered '14 Sep 2020 17:45'	System	14 Sep 2020 21:45:42

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 5'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:51:53', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21b09738-3037-451b-b887-64c2468bbae4'	System	16 Sep 2020 01:52:33
User entered 'Yes (Y)'	System	16 Sep 2020 01:52:33

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:52:05', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21b09738-3037-451b-b887-64c2468bbae4' User entered '97.7'	System	16 Sep 2020 01:52:33
	System	16 Sep 2020 01:52:33



US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:52:18', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21b09738-3037-451b-b887-64c2468bbae4'	System	16 Sep 2020 01:52:33
User entered 'No (N)'	System	16 Sep 2020 01:52:33

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:52:28', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21b09738-3037-451b-b887-64c2468bbae4'	System	16 Sep 2020 01:52:33
User entered '15 Sep 2020 21:52'	System	16 Sep 2020 01:52:33

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 6'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:19:41', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '02854951-c72b-41a0-96b8-bcb11410c2b8' User entered 'Yes (Y)'	System	17 Sep 2020 01:20:38
	System	17 Sep 2020 01:20:38

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:19:48', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '02854951-c72b-41a0-96b8-bcb11410c2b8' User entered '97.4'	System	17 Sep 2020 01:20:38
	System	17 Sep 2020 01:20:38

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:19:54', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '02854951-c72b-41a0-96b8-bcb11410c2b8'	System	17 Sep 2020 01:20:38
User entered 'No (N)'	System	17 Sep 2020 01:20:38



US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 08:00:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:20:01', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '02854951-c72b-41a0-96b8-bcb11410c2b8'	System	17 Sep 2020 01:20:38
User entered '16 Sep 2020 21:20'	System	17 Sep 2020 01:20:38

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 7'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:10:40', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '7e41a97e-5ea1-44fc-8b18-91a34f4b3caf' User entered 'Yes (Y)'	System	18 Sep 2020 01:11:07
	System	18 Sep 2020 01:11:07

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:10:50', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '7e41a97e-5ea1-44fc-8b18-91a34f4b3caf' User entered '98.1'	System	18 Sep 2020 01:11:07
	System	18 Sep 2020 01:11:07

US3512082

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 08:00:37

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:10:56', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '7e41a97e-5ea1-44fc-8b18-91a34f4b3caf' User entered 'No (N)'	System	18 Sep 2020 01:11:07
	System	18 Sep 2020 01:11:07

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:11:03', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '7e41a97e-5ea1-44fc-8b18-91a34f4b3caf' User entered '17 Sep 2020 21:11'	System	18 Sep 2020 01:11:07
	System	18 Sep 2020 01:11:07



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:25:07', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '26263af1-9579-446a-b115-0504844421e8' User entered 'None (1)'	System	11 Sep 2020 18:25:48
	System	11 Sep 2020 18:25:48

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:25:15', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '26263af1-9579-446a-b115-0504844421e8' User entered 'No (N)'	System	11 Sep 2020 18:25:48
	System	11 Sep 2020 18:25:48

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:25:21', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '26263af1-9579-446a-b115-0504844421e8' User entered 'No (N)'	System	11 Sep 2020 18:25:48
	System	11 Sep 2020 18:25:48

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:25:29', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '26263af1-9579-446a-b115-0504844421e8' User entered 'None (1)'	System	11 Sep 2020 18:25:48
	System	11 Sep 2020 18:25:48

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:25:41', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '26263af1-9579-446a-b115-0504844421e8' User entered '11 Sep 2020 14:25'	System	11 Sep 2020 18:25:48
	System	11 Sep 2020 18:25:48



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '11 Sep 2020 14:09'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '11 Sep 2020 16:39'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:31:39', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5a87bdb6-afd4-4384-b032-5f4c6b530ed7'	System	11 Sep 2020 22:32:45
User entered 'None (1)'	System	11 Sep 2020 22:32:45

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:31:44', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5a87bdb6-afd4-4384-b032-5f4c6b530ed7' User entered 'No (N)'	System	11 Sep 2020 22:32:45
	System	11 Sep 2020 22:32:45

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:31:51', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5a87bdb6-afd4-4384-b032-5f4c6b530ed7' User entered 'No (N)'	System	11 Sep 2020 22:32:45
	System	11 Sep 2020 22:32:45

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:31:59', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5a87bdb6-afd4-4384-b032-5f4c6b530ed7'	System	11 Sep 2020 22:32:45
User entered 'None (1)'	System	11 Sep 2020 22:32:45

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:32:09', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5a87bdb6-afd4-4384-b032-5f4c6b530ed7' User entered '11 Sep 2020 18:32'	System	11 Sep 2020 22:32:45
	System	11 Sep 2020 22:32:45



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '11 Sep 2020 17:34'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 2'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:25:11', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '9abd36c5-bbe8-4930-80fe-b78313583581'	System	12 Sep 2020 22:26:16
User entered 'None (1)'	System	12 Sep 2020 22:26:16

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:25:20', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '9abd36c5-bbe8-4930-80fe-b78313583581' User entered 'No (N)'	System	12 Sep 2020 22:26:16
	System	12 Sep 2020 22:26:16

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:25:31', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '9abd36c5-bbe8-4930-80fe-b78313583581' User entered 'No (N)'	System	12 Sep 2020 22:26:16
	System	12 Sep 2020 22:26:16

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:25:59', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '9abd36c5-bbe8-4930-80fe-b78313583581' User entered 'None (1)'	System	12 Sep 2020 22:26:16
	System	12 Sep 2020 22:26:16

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:26:13', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '9abd36c5-bbe8-4930-80fe-b78313583581' User entered '12 Sep 2020 18:26'	System	12 Sep 2020 22:26:16
	System	12 Sep 2020 22:26:16



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 3'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:18:37', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e606022b-1993-4439-b2a2-837881411d15'	System	13 Sep 2020 22:19:13
User entered 'None (1)'	System	13 Sep 2020 22:19:13

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:18:41', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e606022b-1993-4439-b2a2-837881411d15'	System	13 Sep 2020 22:19:13
User entered 'No (N)'	System	13 Sep 2020 22:19:13

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:18:45', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e606022b-1993-4439-b2a2-837881411d15' User entered 'No (N)'	System	13 Sep 2020 22:19:13
	System	13 Sep 2020 22:19:13

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:18:52', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e606022b-1993-4439-b2a2-837881411d15'	System	13 Sep 2020 22:19:13
User entered 'None (1)'	System	13 Sep 2020 22:19:13

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:19:10', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e606022b-1993-4439-b2a2-837881411d15'	System	13 Sep 2020 22:19:13
User entered '13 Sep 2020 18:19'	System	13 Sep 2020 22:19:13



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 4'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:45:48', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'eb92c5c1-505d-457b-bafa-036de1065833'	System	14 Sep 2020 21:46:26
User entered 'None (1)'	System	14 Sep 2020 21:46:26

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:45:54', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'eb92c5c1-505d-457b-bafa-036de1065833' User entered 'No (N)'	System	14 Sep 2020 21:46:26
	System	14 Sep 2020 21:46:26

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:45:59', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'eb92c5c1-505d-457b-bafa-036de1065833' User entered 'No (N)'	System	14 Sep 2020 21:46:26
	System	14 Sep 2020 21:46:26

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:46:07', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'eb92c5c1-505d-457b-bafa-036de1065833' User entered 'None (1)'	System	14 Sep 2020 21:46:26
	System	14 Sep 2020 21:46:26

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:46:21', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'eb92c5c1-505d-457b-bafa-036de1065833'	System	14 Sep 2020 21:46:26
User entered '14 Sep 2020 17:46'	System	14 Sep 2020 21:46:26



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 5'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:52:36', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b2f07997-4490-48cd-ab0f-2bfd4176d5bc'	System	16 Sep 2020 01:53:18
User entered 'None (1)'	System	16 Sep 2020 01:53:18

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:52:42', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b2f07997-4490-48cd-ab0f-2bfd4176d5bc' User entered 'No (N)'	System	16 Sep 2020 01:53:18
	System	16 Sep 2020 01:53:18

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:52:49', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b2f07997-4490-48cd-ab0f-2bfd4176d5bc' User entered 'No (N)'	System	16 Sep 2020 01:53:18
	System	16 Sep 2020 01:53:18

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:52:56', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b2f07997-4490-48cd-ab0f-2bfd4176d5bc'	System	16 Sep 2020 01:53:18
User entered 'None (1)'	System	16 Sep 2020 01:53:18

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:53:16', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b2f07997-4490-48cd-ab0f-2bfd4176d5bc' User entered '15 Sep 2020 21:53'	System	16 Sep 2020 01:53:18
	System	16 Sep 2020 01:53:18



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 6'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:20:11', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1b808d4d-320c-492f-b416-83d73a362e5f' User entered 'None (1)'	System	17 Sep 2020 01:22:29
	System	17 Sep 2020 01:22:29

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:20:21', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1b808d4d-320c-492f-b416-83d73a362e5f' User entered 'No (N)'	System	17 Sep 2020 01:22:29
	System	17 Sep 2020 01:22:29

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:20:26', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1b808d4d-320c-492f-b416-83d73a362e5f' User entered 'No (N)'	System	17 Sep 2020 01:22:29
	System	17 Sep 2020 01:22:29

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:20:31', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1b808d4d-320c-492f-b416-83d73a362e5f' User entered 'None (1)'	System	17 Sep 2020 01:22:29
	System	17 Sep 2020 01:22:29

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:20:49', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1b808d4d-320c-492f-b416-83d73a362e5f' User entered '16 Sep 2020 21:20'	System	17 Sep 2020 01:22:29
	System	17 Sep 2020 01:22:29



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 7'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:11:10', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21921e05-7f50-43b5-afce-9510bce499ad' User entered 'None (1)'	System	18 Sep 2020 01:11:42
	System	18 Sep 2020 01:11:42

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:37

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:11:15', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21921e05-7f50-43b5-afce-9510bce499ad' User entered 'No (N)'	System	18 Sep 2020 01:11:42
	System	18 Sep 2020 01:11:42

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:37

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:11:22', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21921e05-7f50-43b5-afce-9510bce499ad' User entered 'No (N)'	System	18 Sep 2020 01:11:42
	System	18 Sep 2020 01:11:42

US3512082

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:11:28', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21921e05-7f50-43b5-afce-9510bce499ad' User entered 'None (1)'	System	18 Sep 2020 01:11:42
	System	18 Sep 2020 01:11:42

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:11:40', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '21921e05-7f50-43b5-afce-9510bce499ad' User entered '17 Sep 2020 21:11'	System	18 Sep 2020 01:11:42
	System	18 Sep 2020 01:11:42



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:25:48', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'ba9564d5-8882-4443-91c3-f92664c9356d' User entered 'None (0)'	System	11 Sep 2020 18:26:40
	System	11 Sep 2020 18:26:40

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:25:52', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'ba9564d5-8882-4443-91c3-f92664c9356d' User entered 'None (0)'	System	11 Sep 2020 18:26:40
	System	11 Sep 2020 18:26:40

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:25:57', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'ba9564d5-8882-4443-91c3-f92664c9356d' User entered 'None (0)'	System	11 Sep 2020 18:26:40
	System	11 Sep 2020 18:26:40

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:26:09', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'ba9564d5-8882-4443-91c3-f92664c9356d' User entered 'None (0)'	System	11 Sep 2020 18:26:40
	System	11 Sep 2020 18:26:40

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:26:12', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'ba9564d5-8882-4443-91c3-f92664c9356d' User entered 'None (0)'	System	11 Sep 2020 18:26:40
	System	11 Sep 2020 18:26:40



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:26:16', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'ba9564d5-8882-4443-91c3-f92664c9356d' User entered 'None (0)'	System	11 Sep 2020 18:26:40
	System	11 Sep 2020 18:26:40

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:26:22', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'ba9564d5-8882-4443-91c3-f92664c9356d' User entered 'No (N)'	System	11 Sep 2020 18:26:40
	System	11 Sep 2020 18:26:40

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T14:26:37', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'ba9564d5-8882-4443-91c3-f92664c9356d' User entered '11 Sep 2020 14:26'	System	11 Sep 2020 18:26:40
	System	11 Sep 2020 18:26:40

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '11 Sep 2020 14:09'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '11 Sep 2020 16:39'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:32:17', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '545019c3-a89f-4065-9fac-af96cbf0d5cb' User entered 'None (0)'	System	11 Sep 2020 22:33:02
	System	11 Sep 2020 22:33:02

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:32:22', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '545019c3-a89f-4065-9fac-af96cbf0d5cb' User entered 'None (0)'	System	11 Sep 2020 22:33:02
	System	11 Sep 2020 22:33:02



US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:32:25', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '545019c3-a89f-4065-9fac-af96cbf0d5cb' User entered 'None (0)'	System	11 Sep 2020 22:33:02
	System	11 Sep 2020 22:33:02

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:32:28', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '545019c3-a89f-4065-9fac-af96cbf0d5cb' User entered 'None (0)'	System	11 Sep 2020 22:33:02
	System	11 Sep 2020 22:33:02

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:32:31', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '545019c3-a89f-4065-9fac-af96cbf0d5cb' User entered 'None (0)'	System	11 Sep 2020 22:33:02
	System	11 Sep 2020 22:33:02

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:32:34', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '545019c3-a89f-4065-9fac-af96cbf0d5cb' User entered 'None (0)'	System	11 Sep 2020 22:33:02
	System	11 Sep 2020 22:33:02

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:32:39', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '545019c3-a89f-4065-9fac-af96cbf0d5cb' User entered 'No (N)'	System	11 Sep 2020 22:33:02
	System	11 Sep 2020 22:33:02

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-11T18:32:50', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '545019c3-a89f-4065-9fac-af96cbf0d5cb' User entered '11 Sep 2020 18:32'	System	11 Sep 2020 22:33:02
	System	11 Sep 2020 22:33:02

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '11 Sep 2020 17:34'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 17:59:21



US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 2'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:26:19', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c332c1ab-7c5c-4929-b50d-9bc507ae508f' User entered 'None (0)'	System	12 Sep 2020 22:27:16
	System	12 Sep 2020 22:27:16

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:26:23', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c332c1ab-7c5c-4929-b50d-9bc507ae508f' User entered 'None (0)'	System	12 Sep 2020 22:27:16
	System	12 Sep 2020 22:27:16

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:26:26', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c332c1ab-7c5c-4929-b50d-9bc507ae508f' User entered 'None (0)'	System	12 Sep 2020 22:27:16
	System	12 Sep 2020 22:27:16

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:26:29', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c332c1ab-7c5c-4929-b50d-9bc507ae508f' User entered 'None (0)'	System	12 Sep 2020 22:27:16
	System	12 Sep 2020 22:27:16

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:26:32', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c332c1ab-7c5c-4929-b50d-9bc507ae508f' User entered 'None (0)'	System	12 Sep 2020 22:27:16
	System	12 Sep 2020 22:27:16

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:26:35', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c332c1ab-7c5c-4929-b50d-9bc507ae508f' User entered 'None (0)'	System	12 Sep 2020 22:27:16
	System	12 Sep 2020 22:27:16

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:26:51', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c332c1ab-7c5c-4929-b50d-9bc507ae508f' User entered 'No (N)'	System	12 Sep 2020 22:27:16
	System	12 Sep 2020 22:27:16



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-12T18:27:12', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c332c1ab-7c5c-4929-b50d-9bc507ae508f' User entered '12 Sep 2020 18:27'	System	12 Sep 2020 22:27:16
	System	12 Sep 2020 22:27:16

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 3'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:19:16', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '17c4540c-af8d-4bd0-a6ea-fbae6692476e' User entered 'None (0)'	System	13 Sep 2020 22:19:58
	System	13 Sep 2020 22:19:58

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:19:25', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '17c4540c-af8d-4bd0-a6ea-fbae6692476e' User entered 'None (0)'	System	13 Sep 2020 22:19:58
	System	13 Sep 2020 22:19:58

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:19:28', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '17c4540c-af8d-4bd0-a6ea-fbae6692476e' User entered 'None (0)'	System	13 Sep 2020 22:19:58
	System	13 Sep 2020 22:19:58

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:19:34', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '17c4540c-af8d-4bd0-a6ea-fbae6692476e' User entered 'None (0)'	System	13 Sep 2020 22:19:58
	System	13 Sep 2020 22:19:58



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:19:37', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '17c4540c-af8d-4bd0-a6ea-fbae6692476e' User entered 'None (0)'	System	13 Sep 2020 22:19:58
	System	13 Sep 2020 22:19:58

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:19:39', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '17c4540c-af8d-4bd0-a6ea-fbae6692476e' User entered 'None (0)'	System	13 Sep 2020 22:19:58
	System	13 Sep 2020 22:19:58

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:19:44', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '17c4540c-af8d-4bd0-a6ea-fbae6692476e' User entered 'No (N)'	System	13 Sep 2020 22:19:58
	System	13 Sep 2020 22:19:58

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-13T18:19:55', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '17c4540c-af8d-4bd0-a6ea-fbae6692476e' User entered '13 Sep 2020 18:19'	System	13 Sep 2020 22:19:58
	System	13 Sep 2020 22:19:58

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 4'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:46:28', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6489e080-b92a-402c-a5b4-5b458cae7505' User entered 'None (0)'	System	14 Sep 2020 21:47:10
	System	14 Sep 2020 21:47:10



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:46:31', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6489e080-b92a-402c-a5b4-5b458cae7505' User entered 'None (0)'	System	14 Sep 2020 21:47:10
	System	14 Sep 2020 21:47:10

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:46:36', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6489e080-b92a-402c-a5b4-5b458cae7505' User entered 'None (0)'	System	14 Sep 2020 21:47:10
	System	14 Sep 2020 21:47:10

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:46:39', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6489e080-b92a-402c-a5b4-5b458cae7505' User entered 'None (0)'	System	14 Sep 2020 21:47:10
	System	14 Sep 2020 21:47:10

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:46:43', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6489e080-b92a-402c-a5b4-5b458cae7505' User entered 'None (0)'	System	14 Sep 2020 21:47:10
	System	14 Sep 2020 21:47:10

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:46:45', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6489e080-b92a-402c-a5b4-5b458cae7505' User entered 'None (0)'	System	14 Sep 2020 21:47:10
	System	14 Sep 2020 21:47:10

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:46:52', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6489e080-b92a-402c-a5b4-5b458cae7505' User entered 'No (N)'	System	14 Sep 2020 21:47:10
	System	14 Sep 2020 21:47:10

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-14T17:47:05', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6489e080-b92a-402c-a5b4-5b458cae7505' User entered '14 Sep 2020 17:47'	System	14 Sep 2020 21:47:10
	System	14 Sep 2020 21:47:10

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 17:59:21



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 5'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:53:46', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cccdcad-36f7-411c-a505-c58039717fe7' User entered 'None (0)'	System	16 Sep 2020 01:54:39
	System	16 Sep 2020 01:54:39

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:53:50', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cccdcad-36f7-411c-a505-c58039717fe7' User entered 'None (0)'	System	16 Sep 2020 01:54:39
	System	16 Sep 2020 01:54:39

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:53:56', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cccdcad-36f7-411c-a505-c58039717fe7' User entered 'None (0)'	System	16 Sep 2020 01:54:39
	System	16 Sep 2020 01:54:39

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:54:05', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cccdcad-36f7-411c-a505-c58039717fe7' User entered 'None (0)'	System	16 Sep 2020 01:54:39
	System	16 Sep 2020 01:54:39

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:37

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:54:07', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cccdcad-36f7-411c-a505-c58039717fe7' User entered 'None (0)'	System	16 Sep 2020 01:54:39
	System	16 Sep 2020 01:54:39

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:54:10', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cccdcad-36f7-411c-a505-c58039717fe7' User entered 'None (0)'	System	16 Sep 2020 01:54:39
	System	16 Sep 2020 01:54:39



US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:54:15', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cccdcad-36f7-411c-a505-c58039717fe7' User entered 'No (N)'	System	16 Sep 2020 01:54:39
	System	16 Sep 2020 01:54:39

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-15T21:54:37', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cccdcad-36f7-411c-a505-c58039717fe7' User entered '15 Sep 2020 21:54'	System	16 Sep 2020 01:54:39
	System	16 Sep 2020 01:54:39

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 6'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:21:01', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c85a707b-35bb-4ad9-8b4f-c5bf7cd51033' User entered 'None (0)'	System	17 Sep 2020 01:23:18
	System	17 Sep 2020 01:23:18

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:21:07', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c85a707b-35bb-4ad9-8b4f-c5bf7cd51033' User entered 'None (0)'	System	17 Sep 2020 01:23:18
	System	17 Sep 2020 01:23:18

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:21:13', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c85a707b-35bb-4ad9-8b4f-c5bf7cd51033' User entered 'None (0)'	System	17 Sep 2020 01:23:18
	System	17 Sep 2020 01:23:18



US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:21:18', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c85a707b-35bb-4ad9-8b4f-c5bf7cd51033' User entered 'None (0)'	System	17 Sep 2020 01:23:18
	System	17 Sep 2020 01:23:18

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:21:24', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c85a707b-35bb-4ad9-8b4f-c5bf7cd51033' User entered 'None (0)'	System	17 Sep 2020 01:23:18
	System	17 Sep 2020 01:23:18

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:21:28', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c85a707b-35bb-4ad9-8b4f-c5bf7cd51033' User entered 'None (0)'	System	17 Sep 2020 01:23:18
	System	17 Sep 2020 01:23:18

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:21:35', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c85a707b-35bb-4ad9-8b4f-c5bf7cd51033' User entered 'No (N)'	System	17 Sep 2020 01:23:18
	System	17 Sep 2020 01:23:18

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-16T21:22:11', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c85a707b-35bb-4ad9-8b4f-c5bf7cd51033' User entered '16 Sep 2020 21:22'	System	17 Sep 2020 01:23:18
	System	17 Sep 2020 01:23:18

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	11 Sep 2020 17:59:21
User entered 'Day 7'	System	11 Sep 2020 17:59:21



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:11:47', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'dc170847-9529-4a90-a358-090ce692623d' User entered 'None (0)'	System	18 Sep 2020 01:12:37
	System	18 Sep 2020 01:12:37

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:11:59', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'dc170847-9529-4a90-a358-090ce692623d' User entered 'None (0)'	System	18 Sep 2020 01:12:37
	System	18 Sep 2020 01:12:37

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:12:03', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'dc170847-9529-4a90-a358-090ce692623d' User entered 'None (0)'	System	18 Sep 2020 01:12:37
	System	18 Sep 2020 01:12:37

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:37

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:12:07', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'dc170847-9529-4a90-a358-090ce692623d' User entered 'None (0)'	System	18 Sep 2020 01:12:37
	System	18 Sep 2020 01:12:37

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:12:12', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'dc170847-9529-4a90-a358-090ce692623d' User entered 'None (0)'	System	18 Sep 2020 01:12:37
	System	18 Sep 2020 01:12:37

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:12:17', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'dc170847-9529-4a90-a358-090ce692623d' User entered 'None (0)'	System	18 Sep 2020 01:12:37
	System	18 Sep 2020 01:12:37

US3512082

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 08:00:37

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 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:12:24', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'dc170847-9529-4a90-a358-090ce692623d' User entered 'No (N)'	System	18 Sep 2020 01:12:37
	System	18 Sep 2020 01:12:37

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-09-17T21:12:35', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'dc170847-9529-4a90-a358-090ce692623d' User entered '17 Sep 2020 21:12'	System	18 Sep 2020 01:12:37
	System	18 Sep 2020 01:12:37



**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 08:00:37**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 17:59:21

**US3512082**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	21 Sep 2020 19:07:07

**US3512082**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '21 Sep 2020'	Sheldon Warren (b) (4)	21 Sep 2020 19:07:07

US3512082

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	21 Sep 2020 19:07:07

US3512082

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	21 Sep 2020 19:07:07

**US3512082**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	21 Sep 2020 19:07:13

**US3512082**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'I'	System	21 Sep 2020 19:07:13



**US3512082**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	25 Sep 2020 20:45:46

**US3512082**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '25 Sep 2020'	Taylor Johnson (b) (4)	25 Sep 2020 20:45:46

**US3512082**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Taylor Johnson (b) (4)	25 Sep 2020 20:45:46

US3512082

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	25 Sep 2020 20:45:46

**US3512082**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	25 Sep 2020 20:45:36

**US3512082**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'I'	System	25 Sep 2020 20:45:36

US3512082

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 03:06:37
Query 'Data is required. Please complete.' answered with 'data entry error' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 16:14:07
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Oct 2020 23:49:29
User entered empty; reason for change Data Entry Error	System	01 Oct 2020 23:49:22
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	01 Oct 2020 23:49:22
	(b) (4)	
	Sheldon Warren (b) (4)	25 Sep 2020 22:19:23
	(b) (4)	

US3512082

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4)	02 Oct 2020 16:14:07
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 16:14:07
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	01 Oct 2020 23:49:22
answered by data change (Site from System).		
User entered empty; reason for change Data Entry Error	System	01 Oct 2020 23:49:22
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	Taylor Johnson (b) (4)	01 Oct 2020 23:49:22
User entered '25 Sep 2020'	(b) (4)	25 Sep 2020 22:19:23
	System	25 Sep 2020 22:19:23
	Sheldon Warren (b) (4)	25 Sep 2020 22:19:23
	(b) (4)	



US3512082

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:14:07
User entered empty; reason for change Data Entry Error	Taylor Johnson (b) (4) (b) (4)	01 Oct 2020 23:49:22
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4) (b) (4)	25 Sep 2020 22:19:23

US3512082

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	25 Sep 2020 22:19:23

**US3512082**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 16:14:11

**US3512082**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'I'	System	02 Oct 2020 16:14:11

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Allison Crain (b) (4)	09 Oct 2020 18:03:50

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '9 Oct 2020'	Allison Crain (b) (4)	09 Oct 2020 18:03:50

US3512082

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:37

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	09 Oct 2020 18:03:50

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'VISIT3'	System	09 Oct 2020 18:03:50



**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	09 Oct 2020 18:04:30

US3512082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '9 Oct 2020'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Oct 2020 18:04:30

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '13:00'	Allison Crain (b) (4)	09 Oct 2020 18:04:30

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered '9 Oct 2020 13:00'	System	09 Oct 2020 18:04:30

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '97.0' F	Allison Crain (b) (4)	09 Oct 2020 18:04:30

US3512082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Oct 2020 18:04:30

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Allison Crain (b) (4)	09 Oct 2020 18:04:30

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '56'	Allison Crain (b) (4)	09 Oct 2020 18:04:30



**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'bpm'	System	09 Oct 2020 18:04:30

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '12'	Allison Crain (b) (4)	09 Oct 2020 18:04:30

US3512082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'breaths/min'	System	09 Oct 2020 18:04:30

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '154'	Allison Crain (b) (4)	09 Oct 2020 18:04:30

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'mmHg'	System	09 Oct 2020 18:04:30

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '83'	Allison Crain (b) (4)	09 Oct 2020 18:04:30

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'mmHg'	System	09 Oct 2020 18:04:30

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41



US3512082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41

US3512082

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Allison Crain (b) (4)	09 Oct 2020 18:04:41

US3512082

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	09 Oct 2020 18:04:41

US3512082

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Allison Crain (b) (4)	09 Oct 2020 18:04:59

US3512082

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '9 Oct 2020'	(b) (4) Allison Crain (b) (4)	09 Oct 2020 18:04:59

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '13:15'	Allison Crain (b) (4)	09 Oct 2020 18:04:59

**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered '9 Oct 2020 13:15'	System	09 Oct 2020 18:04:59

US3512082

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Allison Crain (b) (4)	09 Oct 2020 18:05:06



**US3512082**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'I'	System	09 Oct 2020 18:05:06

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 64'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-10-16T12:10:15', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cc8c4661-810e-4460-a203-40cfb858398c' User entered 'No (N)'	System	16 Oct 2020 16:11:11
	System	16 Oct 2020 16:11:11

US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-10-16T12:10:41', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cc8c4661-810e-4460-a203-40cfb858398c' User entered 'No (N)'	System	16 Oct 2020 16:11:11
	System	16 Oct 2020 16:11:11

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-10-16T12:11:07', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cc8c4661-810e-4460-a203-40cfb858398c' User entered '16 Oct 2020 12:11:07'	System	16 Oct 2020 16:11:11
	System	16 Oct 2020 16:11:11

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 71'	System	14 Aug 2020 19:18:46



US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-10-21T09:30:04', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b44a68a4-6828-4e73-876c-f14dc5b8e509'	System	21 Oct 2020 13:31:43
User entered 'Yes (Y)'	System	21 Oct 2020 13:31:43

US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-10-21T09:30:21', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b44a68a4-6828-4e73-876c-f14dc5b8e509'	System	21 Oct 2020 13:31:43
User entered 'No (N)'	System	21 Oct 2020 13:31:43

US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-10-21T09:30:33', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b44a68a4-6828-4e73-876c-f14dc5b8e509'	System	21 Oct 2020 13:31:43
User entered 'No (N)'	System	21 Oct 2020 13:31:43

US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-10-21T09:30:43', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b44a68a4-6828-4e73-876c-f14dc5b8e509'	System	21 Oct 2020 13:31:43
User entered 'Yes (Y)'	System	21 Oct 2020 13:31:43

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-10-21T09:31:03', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b44a68a4-6828-4e73-876c-f14dc5b8e509'	System	21 Oct 2020 13:31:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Oct 2020 13:31:43

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-10-21T09:31:33', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b44a68a4-6828-4e73-876c-f14dc5b8e509' User entered '21 Oct 2020 09:31:33'	System	21 Oct 2020 13:31:43
	System	21 Oct 2020 13:31:43

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 19:18:46



**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 78'	System	14 Aug 2020 19:18:46

US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-10-28T09:43:29', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '7128aff7-e538-4746-b551-384af189cac2'	System	28 Oct 2020 13:44:04
User entered 'No (N)'	System	28 Oct 2020 13:44:04

US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-10-28T09:43:39', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '7128aff7-e538-4746-b551-384af189cac2'	System	28 Oct 2020 13:44:04
User entered 'No (N)'	System	28 Oct 2020 13:44:04

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-10-28T09:43:58', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '7128aff7-e538-4746-b551-384af189cac2' User entered '28 Oct 2020 09:43:58'	System	28 Oct 2020 13:44:04
	System	28 Oct 2020 13:44:04

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 92'	System	14 Aug 2020 19:18:46

US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-11T11:12:32', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6b9ff76e-d906-4afb-bff2-d4439503fa02'	System	11 Nov 2020 16:12:59
User entered 'No (N)'	System	11 Nov 2020 16:12:59



**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-11T11:12:41', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6b9ff76e-d906-4afb-bff2-d4439503fa02'	System	11 Nov 2020 16:12:59
User entered 'No (N)'	System	11 Nov 2020 16:12:59

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-11T11:12:58', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6b9ff76e-d906-4afb-bff2-d4439503fa02' User entered '11 Nov 2020 11:12:58'	System	11 Nov 2020 16:12:59
	System	11 Nov 2020 16:12:59

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered 'Day 99'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-18T09:49:23', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '947068d5-80b0-413a-9b65-8dfc30a52c37'	System	18 Nov 2020 14:49:54
User entered 'No (N)'	System	18 Nov 2020 14:49:54

US3512082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:37

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-18T09:49:36', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '947068d5-80b0-413a-9b65-8dfc30a52c37'	System	18 Nov 2020 14:49:54
User entered 'No (N)'	System	18 Nov 2020 14:49:54

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-18T09:49:51', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '947068d5-80b0-413a-9b65-8dfc30a52c37' User entered '18 Nov 2020 09:49:51'	System	18 Nov 2020 14:49:54
	System	18 Nov 2020 14:49:54



**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:55:11
Data entry locked.	System	14 Aug 2020 19:18:46
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 19:18:46

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-19T17:07:16', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '4824573f-9a0d-48a5-b9e7-c6a681d6bcd4' User entered 'No (N)'	System	19 Nov 2020 22:07:49
	System	19 Nov 2020 22:07:49

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-19T17:07:23', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '4824573f-9a0d-48a5-b9e7-c6a681d6bcd4'	System	19 Nov 2020 22:07:49
User entered 'No (N)'	System	19 Nov 2020 22:07:49

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-19T17:07:43', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '4824573f-9a0d-48a5-b9e7-c6a681d6bcd4' User entered '19 Nov 2020 17:07:43'	System	19 Nov 2020 22:07:49
	System	19 Nov 2020 22:07:49

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-22T17:54:26', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'ceab3e2e-2782-40ab-a4f0-735a554578d2'	System	22 Nov 2020 22:54:55
User entered 'No (N)'	System	22 Nov 2020 22:54:55

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-22T17:54:37', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'ceab3e2e-2782-40ab-a4f0-735a554578d2' User entered 'No (N)'	System	22 Nov 2020 22:54:55

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-22T17:54:51', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'ceab3e2e-2782-40ab-a4f0-735a554578d2' User entered '22 Nov 2020 17:54:51'	System	22 Nov 2020 22:54:55
	System	22 Nov 2020 22:54:55

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-29T11:29:43', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6c14c9fb-8ec7-47ab-972a-caa66cc85e35'	System	29 Nov 2020 16:30:10
User entered 'No (N)'	System	29 Nov 2020 16:30:10



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-29T11:29:52', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6c14c9fb-8ec7-47ab-972a-caa66cc85e35'	System	29 Nov 2020 16:30:10
User entered 'No (N)'	System	29 Nov 2020 16:30:10

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-11-29T11:30:07', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6c14c9fb-8ec7-47ab-972a-caa66cc85e35' User entered '29 Nov 2020 11:30:07'	System	29 Nov 2020 16:30:10
	System	29 Nov 2020 16:30:10

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-12-06T09:10:56', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'bd1e1be8-f940-42b9-9f98-36df94088672' User entered 'No (N)'	System	06 Dec 2020 14:11:30
	System	06 Dec 2020 14:11:30

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-12-06T09:11:05', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'bd1e1be8-f940-42b9-9f98-36df94088672'	System	06 Dec 2020 14:11:30
User entered 'No (N)'	System	06 Dec 2020 14:11:30

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-12-06T09:11:26', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'bd1e1be8-f940-42b9-9f98-36df94088672' User entered '06 Dec 2020 09:11:26'	System	06 Dec 2020 14:11:30
	System	06 Dec 2020 14:11:30



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-12-13T19:57:02', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b990af56-f47d-4a58-9c45-90206bcb3d24' User entered 'No (N)'	System	14 Dec 2020 00:57:28
	System	14 Dec 2020 00:57:28

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-12-13T19:57:08', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b990af56-f47d-4a58-9c45-90206bcb3d24'	System	14 Dec 2020 00:57:28
User entered 'No (N)'	System	14 Dec 2020 00:57:28

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-12-13T19:57:25', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'b990af56-f47d-4a58-9c45-90206bcb3d24' User entered '13 Dec 2020 19:57:25'	System	14 Dec 2020 00:57:28
	System	14 Dec 2020 00:57:28

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-12-20T19:52:41', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6bbd0e5c-ebb4-4091-b7d5-2b234fb8d47e' User entered 'No (N)'	System	21 Dec 2020 00:53:04
	System	21 Dec 2020 00:53:04

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-12-20T19:52:50', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6bbd0e5c-ebb4-4091-b7d5-2b234fb8d47e' User entered 'No (N)'	System	21 Dec 2020 00:53:04

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-12-20T19:53:01', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '6bbd0e5c-ebb4-4091-b7d5-2b234fb8d47e' User entered '20 Dec 2020 19:53:01'	System	21 Dec 2020 00:53:04

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-12-27T11:46:04', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1fb6fe0e-1322-4a79-801d-286d31d685e6' User entered 'No (N)'	System	27 Dec 2020 16:46:21
	System	27 Dec 2020 16:46:21



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-12-27T11:46:11', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1fb6fe0e-1322-4a79-801d-286d31d685e6' User entered 'No (N)'	System	27 Dec 2020 16:46:21
	System	27 Dec 2020 16:46:21

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2020-12-27T11:46:15', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '1fb6fe0e-1322-4a79-801d-286d31d685e6' User entered '27 Dec 2020 11:46:15'	System	27 Dec 2020 16:46:21
	System	27 Dec 2020 16:46:21

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-04T22:46:42', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'a5a06a69-09df-4793-b593-37936b552914'	System	05 Jan 2021 03:47:02
User entered 'No (N)'	System	05 Jan 2021 03:47:02

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-04T22:46:49', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'a5a06a69-09df-4793-b593-37936b552914'	System	05 Jan 2021 03:47:02
User entered 'No (N)'	System	05 Jan 2021 03:47:02

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-04T22:46:58', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'a5a06a69-09df-4793-b593-37936b552914' User entered '04 Jan 2021 22:46:58'	System	05 Jan 2021 03:47:02



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-11T22:24:47', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c4696732-9d99-4058-b1c9-630f5a7baa52'	System	12 Jan 2021 03:25:01
User entered 'No (N)'	System	12 Jan 2021 03:25:01

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-11T22:24:53', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c4696732-9d99-4058-b1c9-630f5a7baa52'	System	12 Jan 2021 03:25:01
User entered 'No (N)'	System	12 Jan 2021 03:25:01

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-11T22:24:57', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c4696732-9d99-4058-b1c9-630f5a7baa52' User entered '11 Jan 2021 22:24:57'	System	12 Jan 2021 03:25:01
	System	12 Jan 2021 03:25:01

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-17T08:09:11', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f4d0e9db-bb72-49bd-bf5b-19a9c8a20417'	System	17 Jan 2021 13:09:48
User entered 'No (N)'	System	17 Jan 2021 13:09:48

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-17T08:09:27', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f4d0e9db-bb72-49bd-bf5b-19a9c8a20417'	System	17 Jan 2021 13:09:48
User entered 'No (N)'	System	17 Jan 2021 13:09:48

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-17T08:09:43', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f4d0e9db-bb72-49bd-bf5b-19a9c8a20417' User entered '17 Jan 2021 08:09:43'	System	17 Jan 2021 13:09:48
	System	17 Jan 2021 13:09:48

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-24T10:46:18', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f4e75a71-de49-4beb-8210-ce26355959f1' User entered 'No (N)'	System	24 Jan 2021 15:46:53
	System	24 Jan 2021 15:46:53



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-24T10:46:24', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f4e75a71-de49-4beb-8210-ce26355959f1' User entered 'No (N)'	System	24 Jan 2021 15:46:53

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-24T10:46:49', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'f4e75a71-de49-4beb-8210-ce26355959f1' User entered '24 Jan 2021 10:46:49'	System	24 Jan 2021 15:46:53
	System	24 Jan 2021 15:46:53

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-31T16:06:20', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cbd359d1-fc4d-496f-9172-547b4b83fa4e' User entered 'Yes (Y)'	System	31 Jan 2021 21:07:33
	System	31 Jan 2021 21:07:33

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-31T16:06:33', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cbd359d1-fc4d-496f-9172-547b4b83fa4e' User entered 'No (N)'	System	31 Jan 2021 21:07:33
	System	31 Jan 2021 21:07:33

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-31T16:06:41', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cbd359d1-fc4d-496f-9172-547b4b83fa4e' User entered 'No (N)'	System	31 Jan 2021 21:07:33
	System	31 Jan 2021 21:07:33



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-31T16:06:50', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cbd359d1-fc4d-496f-9172-547b4b83fa4e' User entered 'Yes (Y)'	System	31 Jan 2021 21:07:33
	System	31 Jan 2021 21:07:33

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-31T16:07:09', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cbd359d1-fc4d-496f-9172-547b4b83fa4e'	System	31 Jan 2021 21:07:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 21:07:33

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-01-31T16:07:23', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'cbd359d1-fc4d-496f-9172-547b4b83fa4e' User entered '31 Jan 2021 16:07:23'	System	31 Jan 2021 21:07:33
	System	31 Jan 2021 21:07:33

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-07T12:00:08', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '783fee6d-c314-40c3-b47d-c4e1ccafe784' User entered 'Yes (Y)'	System	07 Feb 2021 17:01:55
	System	07 Feb 2021 17:01:55

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-07T12:00:14', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '783fee6d-c314-40c3-b47d-c4e1ccafe784'	System	07 Feb 2021 17:01:55
User entered 'No (N)'	System	07 Feb 2021 17:01:55



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-07T12:00:22', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '783fee6d-c314-40c3-b47d-c4e1ccafe784'	System	07 Feb 2021 17:01:55
User entered 'No (N)'	System	07 Feb 2021 17:01:55

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-07T12:00:42', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '783fee6d-c314-40c3-b47d-c4e1ccafe784'	System	07 Feb 2021 17:01:55
User entered 'Yes (Y)'	System	07 Feb 2021 17:01:55

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-07T12:00:56', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '783fee6d-c314-40c3-b47d-c4e1ccafe784'	System	07 Feb 2021 17:01:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Feb 2021 17:01:55

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-07T12:01:01', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '783fee6d-c314-40c3-b47d-c4e1ccafe784' User entered '07 Feb 2021 12:01:01'	System	07 Feb 2021 17:01:55
	System	07 Feb 2021 17:01:55

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-15T04:13:52', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e33c96bf-4711-48e0-bc77-d5a2683b05a9' User entered 'No (N)'	System	15 Feb 2021 09:14:20
	System	15 Feb 2021 09:14:20



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-15T04:14:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e33c96bf-4711-48e0-bc77-d5a2683b05a9' User entered 'No (N)'	System	15 Feb 2021 09:14:20
	System	15 Feb 2021 09:14:20

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-15T04:14:15', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'e33c96bf-4711-48e0-bc77-d5a2683b05a9' User entered '15 Feb 2021 04:14:15'	System	15 Feb 2021 09:14:20
	System	15 Feb 2021 09:14:20

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-21T08:44:18', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '4e642114-83b6-4e50-9b39-268379d041c7'	System	21 Feb 2021 13:44:37
User entered 'No (N)'	System	21 Feb 2021 13:44:37

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-21T08:44:26', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '4e642114-83b6-4e50-9b39-268379d041c7'	System	21 Feb 2021 13:44:37
User entered 'No (N)'	System	21 Feb 2021 13:44:37

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-21T08:44:33', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '4e642114-83b6-4e50-9b39-268379d041c7'	System	21 Feb 2021 13:44:37
User entered '21 Feb 2021 08:44:33'	System	21 Feb 2021 13:44:37



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-28T07:25:49-05:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd32fc552-b447-45d4-89af-91017cdd7d92'	System	28 Feb 2021 12:27:01
User entered 'Yes (Y)'	System	28 Feb 2021 12:27:01

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-28T07:25:57-05:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd32fc552-b447-45d4-89af-91017cdd7d92'	System	28 Feb 2021 12:27:01
User entered 'No (N)'	System	28 Feb 2021 12:27:01

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-28T07:26:04-05:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd32fc552-b447-45d4-89af-91017cdd7d92'	System	28 Feb 2021 12:27:01
User entered 'No (N)'	System	28 Feb 2021 12:27:01

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-28T07:26:12-05:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd32fc552-b447-45d4-89af-91017cdd7d92'	System	28 Feb 2021 12:27:01
User entered 'Yes (Y)'	System	28 Feb 2021 12:27:01

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-28T07:26:26-05:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd32fc552-b447-45d4-89af-91017cdd7d92'	System	28 Feb 2021 12:27:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Feb 2021 12:27:01



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-28T07:26:47-05:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd32fc552-b447-45d4-89af-91017cdd7d92'	System	28 Feb 2021 12:27:01
User entered '28 Feb 2021 12:26:47'	System	28 Feb 2021 12:27:01

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-03-07T09:05:21-05:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5733fa44-9711-4bfb-9033-17ac1f0b06cd' User entered 'No (N)'	System	07 Mar 2021 14:05:38
	System	07 Mar 2021 14:05:38

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-03-07T09:05:26-05:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5733fa44-9711-4bfb-9033-17ac1f0b06cd'	System	07 Mar 2021 14:05:38
User entered 'No (N)'	System	07 Mar 2021 14:05:38

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-03-07T09:05:35-05:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5733fa44-9711-4bfb-9033-17ac1f0b06cd' User entered '07 Mar 2021 09:05:35'	System	07 Mar 2021 14:05:38
	System	07 Mar 2021 14:05:38

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-03-16T12:32:20-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '979b16a2-018b-4372-9e7c-bcb04b0ad7c2'	System	16 Mar 2021 16:32:39
User entered 'No (N)'	System	16 Mar 2021 16:32:39

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-03-16T12:32:24-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '979b16a2-018b-4372-9e7c-bcb04b0ad7c2'	System	16 Mar 2021 16:32:39
User entered 'No (N)'	System	16 Mar 2021 16:32:39

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-03-16T12:32:34-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '979b16a2-018b-4372-9e7c-bcb04b0ad7c2' User entered '16 Mar 2021 12:32:34'	System	16 Mar 2021 16:32:39
	System	16 Mar 2021 16:32:39

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-03-21T18:25:23-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5bf884d5-2988-4efb-a861-50fd9a84fe42'	System	21 Mar 2021 22:25:50
User entered 'No (N)'	System	21 Mar 2021 22:25:50

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-03-21T18:25:31-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5bf884d5-2988-4efb-a861-50fd9a84fe42'	System	21 Mar 2021 22:25:50
User entered 'No (N)'	System	21 Mar 2021 22:25:50

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-03-21T18:25:46-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '5bf884d5-2988-4efb-a861-50fd9a84fe42'	System	21 Mar 2021 22:25:50
User entered '21 Mar 2021 18:25:46'	System	21 Mar 2021 22:25:50

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-03-28T08:04:49-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd1fa30c2-07b0-4e9b-96ec-c02aad5c0201'	System	28 Mar 2021 12:05:18
User entered 'No (N)'	System	28 Mar 2021 12:05:18

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-03-28T08:05:05-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd1fa30c2-07b0-4e9b-96ec-c02aad5c0201'	System	28 Mar 2021 12:05:18
User entered 'No (N)'	System	28 Mar 2021 12:05:18



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-03-28T08:05:16-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'd1fa30c2-07b0-4e9b-96ec-c02aad5c0201' User entered '28 Mar 2021 08:05:16'	System	28 Mar 2021 12:05:18
	System	28 Mar 2021 12:05:18

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-06T07:54:31-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '193edc2c-14e6-46bd-b05d-ad9423ab3a39'	System	06 Apr 2021 11:54:57
User entered 'No (N)'	System	06 Apr 2021 11:54:57

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-06T07:54:40-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '193edc2c-14e6-46bd-b05d-ad9423ab3a39'	System	06 Apr 2021 11:54:57
User entered 'No (N)'	System	06 Apr 2021 11:54:57

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-06T07:54:50-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '193edc2c-14e6-46bd-b05d-ad9423ab3a39'	System	06 Apr 2021 11:54:57
User entered '06 Apr 2021 07:54:50'	System	06 Apr 2021 11:54:57

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-11T22:13:10-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '834f3ba7-a4d6-4608-9c65-81353e5146c3'	System	12 Apr 2021 02:14:38
User entered 'Yes (Y)'	System	12 Apr 2021 02:14:38

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-11T22:13:20-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '834f3ba7-a4d6-4608-9c65-81353e5146c3'	System	12 Apr 2021 02:14:38
User entered 'No (N)'	System	12 Apr 2021 02:14:38

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-11T22:13:28-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '834f3ba7-a4d6-4608-9c65-81353e5146c3'	System	12 Apr 2021 02:14:38
User entered 'No (N)'	System	12 Apr 2021 02:14:38

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-11T22:13:41-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '834f3ba7-a4d6-4608-9c65-81353e5146c3'	System	12 Apr 2021 02:14:38
User entered 'Yes (Y)'	System	12 Apr 2021 02:14:38

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-11T22:14:13-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '834f3ba7-a4d6-4608-9c65-81353e5146c3'	System	12 Apr 2021 02:14:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Apr 2021 02:14:38

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-11T22:14:29-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '834f3ba7-a4d6-4608-9c65-81353e5146c3' User entered '11 Apr 2021 22:14:29'	System	12 Apr 2021 02:14:38
	System	12 Apr 2021 02:14:38



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-19T08:44:03-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c9d24f16-109a-467b-90cb-b0a6ee891c91'	System	19 Apr 2021 12:44:25
User entered 'No (N)'	System	19 Apr 2021 12:44:25

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-19T08:44:12-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c9d24f16-109a-467b-90cb-b0a6ee891c91'	System	19 Apr 2021 12:44:25
User entered 'No (N)'	System	19 Apr 2021 12:44:25

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-19T08:44:21-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: 'c9d24f16-109a-467b-90cb-b0a6ee891c91'	System	19 Apr 2021 12:44:25
User entered '19 Apr 2021 08:44:21'	System	19 Apr 2021 12:44:25

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-25T19:23:31-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '486ca17a-c20a-4ccb-b554-1f5f1a8557b7'	System	25 Apr 2021 23:24:26
User entered 'Yes (Y)'	System	25 Apr 2021 23:24:26

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-25T19:23:39-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '486ca17a-c20a-4ccb-b554-1f5f1a8557b7'	System	25 Apr 2021 23:24:26
User entered 'No (N)'	System	25 Apr 2021 23:24:26

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-25T19:23:45-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '486ca17a-c20a-4ccb-b554-1f5f1a8557b7'	System	25 Apr 2021 23:24:26
User entered 'No (N)'	System	25 Apr 2021 23:24:26

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-25T19:23:55-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '486ca17a-c20a-4ccb-b554-1f5f1a8557b7'	System	25 Apr 2021 23:24:26
User entered 'Yes (Y)'	System	25 Apr 2021 23:24:26

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-25T19:24:05-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '486ca17a-c20a-4ccb-b554-1f5f1a8557b7'	System	25 Apr 2021 23:24:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Apr 2021 23:24:26

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-04-25T19:24:17-04:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '486ca17a-c20a-4ccb-b554-1f5f1a8557b7'	System	25 Apr 2021 23:24:26
User entered '25 Apr 2021 19:24:17'	System	25 Apr 2021 23:24:26

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:44:23



**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:44:23

**US3512082**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 08:00:37**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:44:23
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:44:23



US3512082

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:00:37

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:15:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-28T07:27:00-05:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '7ec37f9c-185a-4c1b-9608-d5f35544dda8'	System	28 Feb 2021 12:27:08
User entered 'No (N)'	System	28 Feb 2021 12:27:08

**US3512082**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:15:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABECBE09-4C12-4A2F-A38A-D9B22FB9970F)', Time: '2021-02-28T07:27:06-05:00', User OID: 'PatientReportedOutcome (US3512082)', ODM File OID: '7ec37f9c-185a-4c1b-9608-d5f35544dda8' User entered '28 Feb 2021 12:27:06'	System	28 Feb 2021 12:27:08
	System	28 Feb 2021 12:27:08

**US3512082**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:19:48

**US3512082**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '9 Nov 2020'	Sheldon Warren (b) (4)	09 Nov 2020 19:19:48

**US3512082**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:19:48

**US3512082**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:19:48

**US3512082**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	09 Nov 2020 19:20:30

**US3512082**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:44:41
User entered 'I'	System	09 Nov 2020 19:20:30



**US3512082**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	11 Dec 2020 21:35:15

**US3512082**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '11 Dec 2020'	Sheldon Warren (b) (4)	11 Dec 2020 21:35:15

**US3512082**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4)	11 Dec 2020 21:35:15

US3512082

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	11 Dec 2020 21:35:15

**US3512082**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	11 Dec 2020 21:35:19

**US3512082**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User entered 'I'	System	11 Dec 2020 21:35:19

**US3512082**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	12 Jan 2021 18:43:52

**US3512082**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '12 Jan 2021'	Sheldon Warren (b) (4)	12 Jan 2021 18:43:52



**US3512082**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	12 Jan 2021 18:43:52

**US3512082**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	12 Jan 2021 18:43:52

**US3512082**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	12 Jan 2021 18:43:58

**US3512082**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User entered 'I'	System	12 Jan 2021 18:43:58

**US3512082**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	10 Feb 2021 17:29:08

**US3512082**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '10 Feb 2021'	Sheldon Warren (b) (4)	10 Feb 2021 17:29:08

**US3512082**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	10 Feb 2021 17:29:08

**US3512082**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	10 Feb 2021 17:29:08



**US3512082**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	10 Feb 2021 17:29:14

**US3512082**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User entered '1'	System	10 Feb 2021 17:29:14

US3512082

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User closed query 'Per CDM: Please complete the vital signs assessment form.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 04:04:45
Query 'Per CDM: Please complete the vital signs assessment form.' answered with 'updated' (Site from DM).	Allison Crain (b) (4) (b) (4)	30 Mar 2021 13:40:30
User opened query 'Per CDM: Please complete the vital signs assessment form.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 03:12:30
User signature succeeded.	Michael Koren (b) (4) (b) (4)	05 Mar 2021 22:40:36
User entered 'Yes (Y)'	Allison Crain (b) (4) (b) (4)	05 Mar 2021 15:37:00

**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '3 Mar 2021'	(b) (4) Allison Crain (b) (4)	05 Mar 2021 15:37:00

US3512082

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:37

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered 'Clinic (Clinic)'	(b) (4) Allison Crain (b) (4)	05 Mar 2021 15:37:00

**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User entered 'VISIT4'	System	05 Mar 2021 15:37:00

US3512082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:17
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	30 Mar 2021 13:40:22

US3512082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '03 Mar 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:17
User entered empty.	Allison Crain (b) (4) (b) (4)	30 Mar 2021 13:40:22



**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '10:03' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:17
User entered empty.	Allison Crain (b) (4) (b) (4)	30 Mar 2021 13:40:22

**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User entered '03 Mar 2021 10:03'	System	30 Mar 2021 19:54:17
User entered empty.	System	30 Mar 2021 13:40:22

US3512082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '98.0' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:17
User entered empty.	Allison Crain (b) (4) (b) (4)	30 Mar 2021 13:40:22

US3512082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:17
User entered empty.	Allison Crain (b) (4) (b) (4)	30 Mar 2021 13:40:22

**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	(b) (4) Allison Crain (b) (4)	30 Mar 2021 13:40:22

**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '82' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:17
User entered empty.	Allison Crain (b) (4) (b) (4)	30 Mar 2021 13:40:22

**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User entered 'bpm'	System	30 Mar 2021 19:54:17
User entered empty.	System	30 Mar 2021 13:40:22

US3512082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '16' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:17
User entered empty.	Allison Crain (b) (4) (b) (4)	30 Mar 2021 13:40:22



US3512082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User entered 'breaths/min'	System	30 Mar 2021 19:54:17
User entered empty.	System	30 Mar 2021 13:40:22

US3512082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '132' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:17
User entered empty.	Allison Crain (b) (4) (b) (4)	30 Mar 2021 13:40:22

**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User entered 'mmHg'	System	30 Mar 2021 19:54:17
User entered empty.	System	30 Mar 2021 13:40:22

US3512082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '81' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:54:17
User entered empty.	Allison Crain (b) (4) (b) (4)	30 Mar 2021 13:40:22

US3512082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User entered 'mmHg'	System	30 Mar 2021 19:54:17
User entered empty.	System	30 Mar 2021 13:40:22

**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22

**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22

US3512082

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User closed query 'Per CDM: Physical Examination: Visit 4 Day 209 and OL-D29 are both dated 03Mar2021. However, data in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 07:12:09
Query 'Per CDM: Physical Examination: Visit 4 Day 209 and OL-D29 are both dated 03Mar2021. However, data in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile, else clarify.' answered with 'lymph node exam performed with OL-D29 procedures. No symptom directed PE performed' (Site from DM).	Allison Crain (b) (4) (b) (4)	30 Mar 2021 13:40:03
Signature has been broken.	Allison Crain (b) (4) (b) (4)	30 Mar 2021 13:38:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	30 Mar 2021 13:38:32
User opened query 'Per CDM: Physical Examination: Visit 4 Day 209 and OL-D29 are both dated 03Mar2021. However, data in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile, else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 03:12:57
User signature succeeded.	Michael Koren (b) (4) (b) (4)	05 Mar 2021 22:40:36
User entered 'No (N)'	Allison Crain (b) (4) (b) (4)	05 Mar 2021 15:37:10



US3512082

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Signature has been broken.	Allison Crain (b) (4)	30 Mar 2021 13:38:32
User entered '3 Mar 2021' reason for change: Data Entry Error	Allison Crain (b) (4)	30 Mar 2021 13:38:32
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered empty.	Allison Crain (b) (4)	05 Mar 2021 15:37:10

**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered 'Yes (Y)'	Allison Crain (b) (4)	05 Mar 2021 15:37:29

US3512082

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '3 Mar 2021'	(b) (4) Allison Crain (b) (4)	05 Mar 2021 15:37:29

**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '10:32'	(b) (4) Allison Crain (b) (4)	05 Mar 2021 15:37:29

**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User entered '3 Mar 2021 10:32'	System	05 Mar 2021 15:37:29

US3512082

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	05 Mar 2021 15:37:37

**US3512082**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:45:22
User entered 'I'	System	05 Mar 2021 15:37:37

**US3512082**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:29:17
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:02:55
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	06 Apr 2021 16:33:53



**US3512082**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:29:17
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:02:55
User entered '6 Apr 2021'	(b) (4) Sheldon Warren (b) (4)	06 Apr 2021 16:33:53

**US3512082**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:29:17
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:02:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	06 Apr 2021 16:33:53

US3512082

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:37

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:29:17
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:02:55
User entered empty.	(b) (4) Sheldon Warren (b) (4)	06 Apr 2021 16:33:53

**US3512082**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:29:17
User signature succeeded.	Michael Koren (b) (4)	08 Apr 2021 12:02:55
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	06 Apr 2021 16:33:58

**US3512082**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:29:17
User entered 'I'	System	06 Apr 2021 16:33:58

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:32:33

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '22 Jan 2021'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:32:33

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:37

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Clinic (Clinic)'	Taylor Johnson (b) (4)	27 Jan 2021 13:32:33



**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 13:32:33

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:00:37

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '22 Jan 2021'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:33:31

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:37**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered '0'	Brenda Anderson (b) (4)	10 Mar 2021 14:10:23
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:41:30

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:37**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:33:31

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:37**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
Amendment Manager inserted this DataPoint.	Brenda Anderson (b) (4)	10 Mar 2021 14:10:23
	(b) (4)	
	System	06 Mar 2021 12:41:30

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:00:37

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '22 Jan 2021'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:33:31

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:00:37

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Placebo (Placebo)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:33:31

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:37**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Placebo (Placebo)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:33:31



**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:37**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Placebo (Placebo)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:33:31

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 08:00:37

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:33:31

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:37**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered '1'	System	27 Jan 2021 13:33:31

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'I'	System	27 Jan 2021 13:33:31

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '71' in	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '206' lb	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:00:37**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered '28.79124'	System	27 Jan 2021 13:35:25
DataPoint set to visible.	System	27 Jan 2021 13:33:31

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '71' in	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25



US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '206' lb	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 08:00:37**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered '28.79124'	System	27 Jan 2021 13:35:25
DataPoint set to visible.	System	27 Jan 2021 13:33:31

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Johnson (b) (4) (b) (4)	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '22 Jan 2021'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '10:31'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered '22 Jan 2021 10:31'	System	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '97.4' F	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25



US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (Oral)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '67'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'bpm'	System	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '16'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'breaths/min'	System	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '143'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'mmHg'	System	27 Jan 2021 13:35:25



US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '83'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'mmHg'	System	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:37

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '71' in	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:37

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '206' lb	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered '28.79124'	System	27 Jan 2021 13:35:25
DataPoint set to visible.	System	27 Jan 2021 13:33:31

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Johnson (b) (4) (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '22 Jan 2021'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25



**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '12:09'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered '22 Jan 2021 12:09'	System	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '97.5' F	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (Oral)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '56'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'bpm'	System	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '16'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25



**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'breaths/min'	System	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '146'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'mmHg'	System	27 Jan 2021 13:35:25

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '94'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'mmHg'	System	27 Jan 2021 13:35:25

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:37

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:37**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '22 Jan 2021'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:35:37

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:36:41



US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:36:41

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Taylor Johnson (b) (4)	27 Jan 2021 13:36:41

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'mRNA-1273'	System	27 Jan 2021 13:36:41
DataPoint set to visible.	System	27 Jan 2021 13:33:31

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '22 Jan 2021'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:36:41

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '11:35'	Taylor Johnson (b) (4)	27 Jan 2021 13:36:41

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered '22 Jan 2021 11:35'	System	27 Jan 2021 13:36:41

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Left Arm (LEFT ARM)'	Taylor Johnson (b) (4)	27 Jan 2021 13:36:41

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'ONCE'	System	27 Jan 2021 13:36:41



**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'INTRAMUSCULAR'	System	27 Jan 2021 13:36:41

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:37:11

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '22 Jan 2021'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:37:11

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '10:45'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:37:11

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered '22 Jan 2021 10:45'	System	27 Jan 2021 13:37:11

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:00:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:37:28

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:00:37**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '22 Jan 2021'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:37:28

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:00:37**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '10:53'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:37:28



**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 08:00:37**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered '22 Jan 2021 10:53'	System	27 Jan 2021 13:37:28

US3512082

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	27 Jan 2021 13:37:34

**US3512082**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'I'	System	27 Jan 2021 13:37:34

**US3512082**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	02 Feb 2021 21:35:18

**US3512082**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '1 Feb 2021'	(b) (4) Sheldon Warren (b) (4)	02 Feb 2021 21:35:18

**US3512082**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Contact Made (CONTACT MADE)'	Sheldon Warren (b) (4)	02 Feb 2021 21:35:18

**US3512082**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	02 Feb 2021 21:35:18

**US3512082**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	02 Feb 2021 21:35:30



**US3512082**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'I'	System	02 Feb 2021 21:35:30

**US3512082**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered '1'	System	02 Feb 2021 21:35:30
DataPoint set to visible.	System	02 Feb 2021 21:35:30

**US3512082**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered 'Yes (Y)'	(b) (4) Allison Crain (b) (4)	05 Mar 2021 15:42:07

**US3512082**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '3 Mar 2021'	Allison Crain (b) (4)	05 Mar 2021 15:42:07

**US3512082**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered 'Clinic (Clinic)'	Allison Crain (b) (4)	05 Mar 2021 15:42:07

**US3512082**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'OLD29'	System	05 Mar 2021 15:42:07

US3512082

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User accepted default value 'Pre-Dose (PREDOSE)'	Allison Crain (b) (4) (b) (4)	05 Mar 2021 15:43:32

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered 'Yes (Y)'	Allison Crain (b) (4)	05 Mar 2021 15:43:32



**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '3 Mar 2021'	Allison Crain (b) (4)	05 Mar 2021 15:43:32

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '10:03'	Allison Crain (b) (4)	05 Mar 2021 15:43:32

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered '3 Mar 2021 10:03'	System	05 Mar 2021 15:43:32

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '98.0' F	Allison Crain (b) (4)	05 Mar 2021 15:43:32

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered 'Oral (Oral)'	(b) (4) Allison Crain (b) (4)	05 Mar 2021 15:43:32

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered empty.	Allison Crain (b) (4)	05 Mar 2021 15:43:32

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '82'	Allison Crain (b) (4)	05 Mar 2021 15:43:32

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'bpm'	System	05 Mar 2021 15:43:32



**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '16'	Allison Crain (b) (4)	05 Mar 2021 15:43:32

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'breaths/min'	System	05 Mar 2021 15:43:32

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '132'	(b) (4) Allison Crain (b) (4)	05 Mar 2021 15:43:32

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'mmHg'	System	05 Mar 2021 15:43:32

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '81'	(b) (4) Allison Crain (b) (4)	05 Mar 2021 15:43:32

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'mmHg'	System	05 Mar 2021 15:43:32

US3512082

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User accepted default value 'Post-Dose (POSTDOSE)'	Allison Crain (b) (4) (b) (4)	05 Mar 2021 15:44:14

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered 'Yes (Y)'	Allison Crain (b) (4)	05 Mar 2021 15:44:14



**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '3 Mar 2021'	Allison Crain (b) (4)	05 Mar 2021 15:44:14

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '11:48'	Allison Crain (b) (4)	05 Mar 2021 15:44:14

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered '3 Mar 2021 11:48'	System	05 Mar 2021 15:44:14

US3512082

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '97.9' F	Allison Crain (b) (4)	05 Mar 2021 15:44:14

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered 'Oral (Oral)'	Allison Crain (b) (4)	05 Mar 2021 15:44:14

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered empty.	(b) (4) Allison Crain (b) (4)	05 Mar 2021 15:44:14

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '65'	Allison Crain (b) (4)	05 Mar 2021 15:44:14

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'bpm'	System	05 Mar 2021 15:44:14



**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '12'	Allison Crain (b) (4)	05 Mar 2021 15:44:14

US3512082

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'breaths/min'	System	05 Mar 2021 15:44:14

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '117'	Allison Crain (b) (4)	05 Mar 2021 15:44:14

US3512082

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'mmHg'	System	05 Mar 2021 15:44:14

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '84'	Allison Crain (b) (4)	05 Mar 2021 15:44:14

**US3512082**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'mmHg'	System	05 Mar 2021 15:44:14

**US3512082**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered 'Yes (Y)'	Allison Crain (b) (4)	05 Mar 2021 15:44:26

**US3512082**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:37**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '3 Mar 2021'	Allison Crain (b) (4)	05 Mar 2021 15:44:26



**US3512082**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered 'Yes (Y)'	Allison Crain (b) (4)	05 Mar 2021 15:44:50

**US3512082**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered empty.	Allison Crain (b) (4)	05 Mar 2021 15:44:50

US3512082

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered empty.	Allison Crain (b) (4)	05 Mar 2021 15:44:50

**US3512082**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'mRNA-1273'	System	05 Mar 2021 15:44:50
DataPoint set to visible.	System	02 Feb 2021 21:35:30

US3512082

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '3 Mar 2021'	(b) (4) Allison Crain (b) (4)	05 Mar 2021 15:44:50

**US3512082**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered '11:15'	Allison Crain (b) (4)	05 Mar 2021 15:44:50

**US3512082**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 08:00:37**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered '3 Mar 2021 11:15'	System	05 Mar 2021 15:44:50

US3512082

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered 'Left Arm (LEFT ARM)'	Allison Crain (b) (4)	05 Mar 2021 15:44:50



US3512082

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'ONCE'	System	05 Mar 2021 15:44:50

US3512082

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'INTRAMUSCULAR'	System	05 Mar 2021 15:44:50

**US3512082**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	05 Mar 2021 22:40:36
User entered 'Yes (Y)'	Allison Crain (b) (4)	05 Mar 2021 15:44:57

**US3512082**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'I'	System	05 Mar 2021 15:44:57

**US3512082**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 18:57:46

**US3512082**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered '12 Mar 2021'	Sheldon Warren (b) (4)	12 Mar 2021 18:57:46

**US3512082**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 18:57:46

**US3512082**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 08:00:37**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered empty.	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 18:57:46



**US3512082**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 18:57:51

**US3512082**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 08:00:37**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:02:58
User entered 'I'	System	12 Mar 2021 18:57:51

**US3512082**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 19:50:07

**US3512082**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered '31 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:07

**US3512082**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:07

**US3512082**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 08:00:37**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	31 Mar 2021 19:50:07

**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:17

**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:17



**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:17

**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:50:17

US3512082

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:37

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:17

**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:17

**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:50:17

**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:17

**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:50:17

**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:17



**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:50:17

**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:17

**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:50:17

**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:17

**US3512082**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 08:00:37**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:50:17

**US3512082**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:37**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:23

**US3512082**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 08:00:37**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:50:23

**US3512082**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:38



**US3512082**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered '31 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:50:38

**US3512082**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
	(b) (4)	
User entered '10:26'	(b) (4), (b) (6)	31 Mar 2021 19:50:38

**US3512082**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 08:00:37**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '31 Mar 2021 10:26'	System	31 Mar 2021 19:50:38

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 08:00:37**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:13
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:34
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)' reason for change: New Information	Sheldon Warren (b) (4)	20 Oct 2020 17:04:27
User entered 'No (N)'	Allison Crain (b) (4)	09 Oct 2020 18:05:17

US3512082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:37

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 22:54:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 22:54:28
Data point term sent to Coder	System	20 Oct 2020 17:07:06
User entered 'exercise worsened back muscle spasms'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '19 Oct 2020'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:06:23

US3512082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:37

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)' reason for change: New Information	Sheldon Warren (b) (4)	09 Nov 2020 19:33:41
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 17:06:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 17:06:35
User entered 'Yes (Y)' reason for change: Per Query Resolution	Sheldon Warren (b) (4)	20 Oct 2020 17:06:35
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 17:06:23
User entered empty.	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '29 Oct 2020' reason for change: New Information	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:33:41
User entered empty.	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:06:23



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Not Related (NOT RELATED)'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'I'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
New Information	Sheldon Warren (b) (4)	09 Nov 2020 19:33:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 17:06:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 17:06:23

US3512082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:37

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Eye and eyelid infections, PT: Hordeolum, LLT: Hordeolum - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 05:53:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 05:53:31
Data point term sent to Coder	System	09 Nov 2020 19:34:33
User entered 'right hordeolum'	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '30 Oct 2020'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	04 Dec 2020 15:38:32
User entered 'Yes (Y)'	(b) (4)	
	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	04 Dec 2020 15:38:42
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	04 Dec 2020 15:38:42
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	04 Dec 2020 15:38:32
User entered '11 Nov 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	04 Dec 2020 15:38:32
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:34:32
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 19:34:32

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:34:32



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'I'	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Allison Crain (b) (4)	04 Dec 2020 15:38:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 19:34:32

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 19:34:32



US3512082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:37

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Eye and eyelid infections, PT: Hordeolum, LLT: Hordeolum - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 05:36:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 05:36:25
Data point term sent to Coder	System	09 Nov 2020 19:35:34
User entered 'Left hordeolum'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '4 Nov 2020'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4)	04 Dec 2020 15:39:00
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '11 Nov 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	04 Dec 2020 15:39:00
User entered empty.	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:35:23



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Not Related (NOT RELATED)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'I'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:37

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Allison Crain (b) (4)	04 Dec 2020 15:39:00
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Sheldon Warren (b) (4)	09 Nov 2020 19:35:23
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:35:23



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 19:35:23

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 19:35:23

US3512082

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:00:37

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:05:15
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 13:09:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 13:08:10
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 13:08:07
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:04
User entered 'USA-US065-2021-mRNA-1273-P301000004'	System	11 Feb 2021 17:18:55
User entered 'New'	(b) (4), (b) (6)	11 Feb 2021 17:18:55

US3512082

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:00:37

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Acute retention of urine - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 19:58:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 19:58:56
Data point term sent to Coder	System	10 Feb 2021 20:48:00
User entered 'acute urinary retention'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

US3512082

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:00:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

US3512082

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Start date for acute urinary retention was reported as 26 Jan 2021 and received treatment medication. Subject visited the ED on 27 Jan 2021. Please confirm start date of event.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 15:08:58
Query 'PV Query: Start date for acute urinary retention was reported as 26 Jan 2021 and received treatment medication. Subject visited the ED on 27 Jan 2021. Please confirm start date of event.' answered with 'went to the ED on 26 Jan 21 and was discharged on Bactrim. Pt. returned to ED on 27 Jan 21. 26 JAN 21 is the correct start date for this SAE' (Site from Safety).	Allison Crain (b) (4) (b) (4)	16 Apr 2021 14:36:00
User opened query 'PV Query: Start date for acute urinary retention was reported as 26 Jan 2021 and received treatment medication. Subject visited the ED on 27 Jan 2021. Please confirm start date of event.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 14:28:40
User closed query 'PV Query: Start date for acute urinary retention was reported as 26 Jan 2021 and received treatment medication. Subject visited the ED on 27 Jan 2021. Please confirm start date of event.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 22:05:01
Query 'PV Query: Start date for acute urinary retention was reported as 26 Jan 2021 and received treatment medication. Subject visited the ED on 27 Jan 2021. Please confirm start date of event.' answered with 'pt went to er on 26 jan 2021. pt was written prescription and referred to urology. the next day pt went back to the ER. confirm as is. ' (Site from Safety).	Brenda Anderson (b) (4) (b) (4)	08 Apr 2021 17:46:43
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User opened query 'PV Query: Start date for acute urinary retention was reported as 26 Jan 2021 and received treatment medication. Subject visited the ED on 27 Jan 2021. Please confirm start date of event.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:38:38
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:48:27
User entered '26 Jan 2021'	Brenda Anderson (b) (4) (b) (4)	10 Feb 2021 20:47:41



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 20:47:41

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
Signature has been broken.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:57:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:57:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Feb 2021 20:47:41

US3512082

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:52:28
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:57:04
User entered '07 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:57:04
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'Patient returned to ER for urinary retention on 26FEB2021. Records from follow up with Urologist pending.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:27:57
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 19:46:15
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 16:40:40

US3512082

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'See above. Ongoing answered as "YES". End date not applicable. Please remove query. Adding another query will not help the subject recover any sooner.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 15:01:22
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 21:50:56
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Feb 2021 20:47:41

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 20:47:41

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Grade 4 (Grade 4)'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

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**Form: Adverse Events (4)**

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'I'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

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**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '2 Feb 2021'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

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Form: Adverse Events (4)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for re-requesting medical records. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records are sent.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:57:01
Query 'PV Query: Thank you for re-requesting medical records. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records are sent.'	Allison Crain (b) (4)	22 Apr 2021 14:48:21
answered with 'Records sent ' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Thank you for re-requesting medical records. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records are sent.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 14:29:34
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.	(b) (4), (b) (6)	31 Mar 2021 21:52:32
' (Site from Safety).		

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Medical records re-requested again today on 29MAR2021.' (Site from Safety). Comment added 'awaiting medical records, request medical records x3'.	(b) (4), (b) (6)	29 Mar 2021 18:23:38
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	Brenda Anderson (b) (4)	19 Mar 2021 13:44:56
User signature succeeded.	(b) (4)	
User entered '4 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 21:54:40
	Michael Koren (b) (4)	12 Feb 2021 20:48:27
	(b) (4)	
	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41



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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

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**Form: Adverse Events (4)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

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Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

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Form: Adverse Events (4)

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 22 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 16:49:14
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 22 Jan 2021, then event occurred).' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 15:07:43
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 15:07:32
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 15:07:32
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 22 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 21:57:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Not Applicable (NOT APPLICABLE)'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'I'	Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:00:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Indwelling Catheterization added to Con Proc eCRF' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 04:33:05
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Indwelling Catheterization added to Con Proc eCRF' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:32:41
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	08 Mar 2021 23:22:58
User entered 'I'	Michael Koren (b) (4) Brenda Anderson (b) (4)	12 Feb 2021 20:48:27 10 Feb 2021 20:47:41

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:52:38
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:57:04
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:57:04
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Resolution pending. answering query to submit updated transmission. ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 19:51:09
Comment added 'ongoing as of 03/19/2021 per source'.	Brenda Anderson (b) (4)	19 Mar 2021 14:08:56
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 21:51:06
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Brenda Anderson (b) (4)	10 Feb 2021 20:47:41

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**Form: Adverse Events (4)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
Signature has been broken.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:57:04
User entered 'chronic urinary retention - moderate' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:57:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Feb 2021 20:47:41

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: In case narrative, subject received treatment Bactrim on 26 Jan 2021 and first visited ER on 27 Jan 2021 and returned to 27 Jan 2021. Please clarify date of ER visit and treatment dates.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 15:09:07
Query 'PV Query: In case narrative, subject received treatment Bactrim on 26 Jan 2021 and first visited ER on 27 Jan 2021 and returned to 27 Jan 2021. Please clarify date of ER visit and treatment dates.' answered with 'Per narrative the subject first visited the ER on 26 JAN 21 and was discharged, subject then went to the ER again on 27 JAN 21' (Site from Safety).	Allison Crain (b) (4)	16 Apr 2021 14:58:14
User opened query 'PV Query: In case narrative, subject received treatment Bactrim on 26 Jan 2021 and first visited ER on 27 Jan 2021 and returned to 27 Jan 2021. Please clarify date of ER visit and treatment dates.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 14:29:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:15:09
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:39:32
User closed query 'PV Query: Thank you for re-requesting medical records. When available, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:25:01
User closed query 'PV Query: Thank you for re-requesting medical records. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records are sent.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:24:56

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Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Thank you for re-requesting medical records. When available, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent.' answered with 'Medical records requested numerous times. Site has not received them yet. We have exceeded our required amount of requesting, but we are still trying.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 18:26:57
Query 'PV Query: Thank you for re-requesting medical records. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records are sent.' answered with 'Medical records requested numerous times. Site has not received them yet. We have exceeded our required amount of requesting, but we are still trying.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 18:26:43
User closed query 'PV Query: In case narrative, subject received treatment Bactrim on 26 Jan 2021 and first visited ER on 27 Jan 2021 and returned to 27 Jan 2021. Please clarify date of ER visit and treatment dates.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 22:05:09
Query 'PV Query: In case narrative, subject received treatment Bactrim on 26 Jan 2021 and first visited ER on 27 Jan 2021 and returned to 27 Jan 2021. Please clarify date of ER visit and treatment dates.' answered with 'First ER visit corrected to 26/JAN/2021. Subject returned to ER on the following day 27/JAN/2021' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 18:07:27
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 18:07:21
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 18:07:21

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'FIRST REPORTED TO EMERGENCY ROOM 1/26/21 WITH HEMATURIA/URINARY RETENTION. TREATED WITH INDWELLING CATHETER AND BACTRIM DS. FOLLOW UP WITH UROLOGY CLINIC SCHEDULED FOR "TRIAL OF VOID" AND CATHETER REMOVAL.   HAD TO RETURN TO ER ON 1/27/21 AND 02/02/21 DUE TO CLOTS IN CATHETER CAUSING ACUTE URINARY RETENTION. ADMITED 2/2/21 FOR CONTINUOUS LAVAGE. DISCHARGED ON 02/04/21 WITH INDWELLING CATHETER AND EQUIPMENT FOR AT HOME LAVAGE. CONCERN WAS THAT FINDINGS MAY HAVE BEEN RELATED TO THE PAST RADIATION THERAPY IN 2007 FOR PROSTATE CANCER AND EXACERBATED BY THE EFFIENT AND ASPIRIN TAKEN FOR HEART DISEASE. EFFIENT WAS DISCONTINUED AND ASPIRIN WAS DECREASED TO EVERY OTHER DAY AFTER CONSULTATION WITH CARDIOLOGY. FURTHER WORKUP SCHEDULED.' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:07:21
	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User opened query 'PV Query: Thank you for re-requesting medical records. When available, please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:39:51

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Thank you for re-requesting medical records. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records are sent.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:39:43
User opened query 'PV Query: In case narrative, subject received treatment Bactrim on 26 Jan 2021 and first visited ER on 27 Jan 2021 and returned to 27 Jan 2021. Please clarify date of ER visit and treatment dates.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:39:31
Query 'PV Query: Start date for acute urinary retention was reported as 26 Jan 2021 and received treatment medication. Subject visited the ED on 27 Jan 2021. Please confirm start date of event.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:39:24
User opened query 'PV Query: Start date for acute urinary retention was reported as 26 Jan 2021 and received treatment medication. Subject visited the ED on 27 Jan 2021. Please confirm start date of event.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:39:13
User closed query 'Per DM CLR: Narrative = SCHEDULED FOR WORK UP. However, please verify what are these "WORK UP" and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 02:53:36
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 21:52:42
User signature succeeded.	Michael Koren (b) (4) (b) (4)	31 Mar 2021 17:29:43



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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = CONTINUOUS LAVAGE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 02:48:22
User closed query 'Per DM CLR RQ: Thanks for the response. Kindly note that the drug EFFIENT, mentioned in narration was not recorded in ConMed eCRF. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 02:47:41
User closed query 'Per DM CLR: Narrative = HEMATURIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 02:46:56
Query 'Per DM CLR: Narrative = HEMATURIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Hematuria added to SAE report' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 19:50:46
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Site re-requested medical records again today.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 19:08:47
Query 'Per DM CLR: Narrative = SCHEDULED FOR WORK UP. However, please verify what are these "WORK UP" and ensure that this is captured in the appropriate eCRF. ' answered with "'trial of void" replaced "work up" and date of ER visit corrected to the 27th of January 2021.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 19:06:27
Signature has been broken.	(b) (4), (b) (6)	29 Mar 2021 19:05:56

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'FIRST REPORTED TO EMERGENCY ROOM 1/27/21 WITH HEMATURIA/URINARY RETENTION. TREATED WITH INDWELLING CATHETER AND BACTRIM DS. FOLLOW UP WITH UROLOGY CLINIC SCHEDULED FOR "trial of void" AND CATHETER REMOVAL.   HAD TO RETURN TO ER ON 1/27/21 AND 02/02/21 DUE TO CLOTS IN CATHETER CAUSING ACUTE URINARY RETENTION. ADMITTED 2/2/21 FOR CONTINUOUS LAVAGE. DISCHARGED ON 02/04/21 WITH INDWELLING CATHETER AND EQUIPMENT FOR AT HOME LAVAGE. CONCERN WAS THAT FINDINGS MAY HAVE BEEN RELATED TO THE PAST RADIATION THERAPY IN 2007 FOR PROSTATE CANCER AND EXACERBATED BY THE EFFIENT AND ASPIRIN TAKEN FOR HEART DISEASE. EFFIENT WAS DISCONTINUED AND ASPIRIN WAS DECREASED TO EVERY OTHER DAY AFTER CONSULTATION WITH CARDIOLOGY. FURTHER WORKUP SCHEDULED.' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 19:05:56
Query 'Per DM CLR RQ: Thanks for the response. Kindly note that the drug EFFIENT, mentioned in narration was not recorded in ConMed eCRF. Please review and reconcile.' answered with 'Effient was recorded in the ConMed eCRF. Please see log line for Prasugrel, also known as Effient. Log line updated to include brand name for those asking and not aware.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 18:41:51
Query 'Per DM CLR: Narrative = CONTINUOUS LAVAGE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Continuous Bladder Lavage added to Concomitant Procedure eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 18:33:53

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Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 19:45:02
User closed query 'Per DM CLR: Narrative = PAST RADIATION THERAPY IN 2007. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 02:47:53
User opened query 'Per DM CLR RQ: Thanks for the response. Kindly note that the drug EFFIENT, mentioned in narration was not recorded in ConMed eCRF. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 04:46:14
User closed query 'Per DM CLR: Narrative = EFFIENT WAS DISCONTINUED AND ASPIRIN WAS DECREASED TO EVERY OTHER DAY AFTER CONSULTATION WITH CARDIOLOGY. However, this does not correspond to the recording in the CM eCRF. Review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 04:46:14
User closed query 'Per DM CLR: Narrative = 02/04/21 WITH INDWELLING CATHETER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 04:34:25
User closed query 'Per DM CLR: Narrative = BACTRIM DS. However, the recorded dose in the CM eCRF does not correspond to this Drug name. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 04:34:15
User closed query 'Per DM CLR: Narrative = TREATED WITH INDWELLING CATHETER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 04:31:50

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:00:37

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). Query 'Per DM CLR: Narrative = EFFIENT WAS DISCONTINUED AND ASPIRIN WAS DECREASED TO EVERY OTHER DAY AFTER CONSULTATION WITH CARDIOLOGY. However, this does not correspond to the recording in the CM eCRF. Review and reconcile data as appropriate.' answered with 'Data updated' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 16:49:19
Query 'Per DM CLR: Narrative = PAST RADIATION THERAPY IN 2007. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate. ' answered with 'No. See medical history of Prostate Cancer.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:16:51
Query 'Per DM CLR: Narrative = 02/04/21 WITH INDWELLING CATHETER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. '	(b) (4), (b) (6)	16 Mar 2021 16:07:14
answered with 'Data updated' (Site from DM). Query 'Per DM CLR: Narrative = BACTRIM DS. However, the recorded dose in the CM eCRF does not correspond to this Drug name. Please review and reconcile data as appropriate.' answered with 'Spelling corrected. See log line 25 of CM eCRF.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:06:11
	(b) (4), (b) (6)	16 Mar 2021 16:02:05

US3512082

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:00:37

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = TREATED WITH INDWELLING CATHETER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'data updated. query is a redundant repeat or previous query. please be more creative when duplicating the same query on different log lines.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:59:10
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Records re-requested' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 15:58:11
User opened query 'Per DM CLR: Narrative = EFFIENT WAS DISCONTINUED AND ASPIRIN WAS DECREASED TO EVERY OTHER DAY AFTER CONSULTATION WITH CARDIOLOGY. However, this does not correspond to the recording in the CM eCRF. Review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 23:24:51
User opened query 'Per DM CLR: Narrative = PAST RADIATION THERAPY IN 2007. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 23:24:44
User opened query 'Per DM CLR: Narrative = 02/04/21 WITH INDWELLING CATHETER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 23:24:26
User opened query 'Per DM CLR: Narrative = CONTINUOUS LAVAGE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 23:24:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:00:37

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = SCHEDULED FOR WORK UP. However, please verify what are these "WORK UP" and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 23:24:13
User opened query 'Per DM CLR: Narrative = BACTRIM DS. However, the recorded dose in the CM eCRF does not correspond to this Drug name. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 23:24:08
User opened query 'Per DM CLR: Narrative = TREATED WITH INDWELLING CATHETER. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 23:24:02
User opened query 'Per DM CLR: Narrative = HEMATURIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 23:23:12
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 21:52:03
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:48:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:00:37

[Narrative](#)

Audit	User	Time (GMT)
User entered 'First reported to emergency room 1/26/21 with hematuria/urinary retention. Treated with indwelling catheter and Bactrim DS. Follow up with Urology clinic scheduled for work up and catheter removal.    Had to return to ER on 1/27/21 and 02/02/21 due to clots in catheter causing acute urinary retention. Admitted 2/2/21 for continuous lavage. Discharged on 02/04/21 with indwelling catheter and equipment for at home lavage. Concern was that findings may have been related to the past radiation therapy in 2007 for prostate cancer and exacerbated by the effient and aspirin taken for heart disease. Effient was discontinued and aspirin was decreased to every other day after consultation with cardiology. Further workup scheduled.'	Brenda Anderson (b) (4)	(b) (4) 10 Feb 2021 20:47:41

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Feb 2021 20:47:41



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Feb 2021 20:47:41

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 20:47:41

US3512082

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:00:37

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Escherichia infections, PT: Escherichia infection, LLT: Escherichia coli infection - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 21:32:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 21:32:55
Data point term sent to Coder	System	01 Mar 2021 21:16:58
User entered 'Escherichia coli infection'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'No (N)'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'No (N)'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '18 Feb 2021'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'No (N)'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Dose Delayed (DOSE DELAYED)'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:00:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 04:40:19
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'adding number 29 to con meds form' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	19 Mar 2021 13:50:57
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:29:11
User entered 'I'	Brenda Anderson (b) (4) (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Mar 2021 21:16:49

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 21:16:49

US3512082

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:00:37

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User coded data point as SOC: Renal and urinary disorders, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stone - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 12:23:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 12:23:37
Data point term sent to Coder	System	08 Mar 2021 12:22:19
User entered 'kidney stone'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'No (N)'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'No (N)'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '16 Feb 2021'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 12:21:56

US3512082

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:00:37

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Mar 2021 15:53:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 15:53:31
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	08 Mar 2021 15:53:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Mar 2021 12:21:56
User entered empty.	System	08 Mar 2021 12:21:56
	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56
	(b) (4)	



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'No (N)'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

US3512082

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:00:37

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:00:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Mar 2021 15:53:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 15:53:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	08 Mar 2021 15:53:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Mar 2021 12:21:56
User entered empty.	System	08 Mar 2021 12:21:56
	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:00:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Mar 2021 15:53:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 15:53:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	08 Mar 2021 15:53:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Mar 2021 12:21:56
User entered empty.	System	08 Mar 2021 12:21:56
	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:00:37

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Mar 2021 15:53:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 15:53:31
User entered 'None (NONE)' reason for change:	Brenda Anderson (b) (4)	08 Mar 2021 15:53:31
Data Entry Error	(b) (4)	08 Mar 2021 12:21:56
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 12:21:56
User entered empty.	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'I'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

US3512082

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:00:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

US3512082

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:00:37

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Mar 2021 15:53:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Mar 2021 15:53:31
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Brenda Anderson (b) (4)	08 Mar 2021 15:53:31
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Mar 2021 12:21:56
User entered empty.	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	Brenda Anderson (b) (4)	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Mar 2021 12:21:56

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 13:09:25
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 13:09:21
Reviewed for Safety.	(b) (4), (b) (6)	01 Apr 2021 13:08:02
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'USA-US065-2021-mRNA-1273-P301000004'	(b) (4), (b) (6)	30 Mar 2021 14:31:20

US3512082

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:00:37

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary abnormalities, PT: Haematuria, LLT: Hematuria - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 19:49:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 19:49:28
Data point term sent to Coder	System	29 Mar 2021 19:47:38
User entered 'Hematuria'	(b) (4), (b) (6)	29 Mar 2021 19:47:01



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
Signature has been broken.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:57:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:57:54
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
Signature has been broken.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:57:54
User entered '08 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:57:54
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

US3512082

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:00:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	29 Mar 2021 19:47:21
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	29 Mar 2021 19:47:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

US3512082

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:00:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	29 Mar 2021 19:47:21
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		29 Mar 2021 19:47:21
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 19:47:21
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	29 Mar 2021 19:47:01
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01



US3512082

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:00:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for re-requesting medical records. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records are sent.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:57:47
Query 'PV Query: Thank you for re-requesting medical records. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records are sent.' answered with 'Records sent' (Site from Safety).	Allison Crain (b) (4)	22 Apr 2021 14:49:21
User opened query 'PV Query: Thank you for re-requesting medical records. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records are sent.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 14:29:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '04 Feb 2021'	(b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
Signature has been broken.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:57:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:57:54
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

US3512082

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:00:37

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'FIRST REPORTED TO EMERGENCY ROOM 1/27/21 WITH HEMATURIA/URINARY RETENTION. TREATED WITH INDWELLING CATHETER AND BACTRIM DS. FOLLOW UP WITH UROLOGY CLINIC SCHEDULED FOR "TRIAL OF VOID" AND CATHETER REMOVAL.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:47:01

HAD TO RETURN TO ER ON 1/27/21 AND  
02/02/21 DUE TO CLOTS IN CATHETER  
CAUSING ACUTE URINARY RETENTION.  
ADMITTED 2/2/21 FOR CONTINUOUS LAVAGE.  
DISCHARGED ON 02/04/21 WITH INDWELLING  
CATHETER AND EQUIPMENT FOR AT HOME  
LAVAGE. CONCERN WAS THAT FINDINGS  
MAY HAVE BEEN RELATED TO THE PAST  
RADIATION THERAPY IN 2007 FOR PROSTATE  
CANCER AND EXACERBATED BY THE  
EFFIENT AND ASPIRIN TAKEN FOR HEART  
DISEASE. EFFIENT WAS DISCONTINUED AND  
ASPIRIN WAS DECREASED TO EVERY OTHER  
DAY AFTER CONSULTATION WITH  
CARDIOLOGY. FURTHER WORKUP  
SCHEDULED.'

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 19:47:01



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 19:47:01

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Mar 2021 19:47:01

US3512082

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:00:37

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\23.0.	Coder Import (b) (4)	01 Apr 2021 12:10:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	01 Apr 2021 12:10:31
Data point term sent to Coder	System	31 Mar 2021 20:02:20
User entered 'Chronic urinary retention'	(b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

US3512082

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:00:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Mar 2021 20:02:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 20:02:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 20:02:02
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 20:01:53
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered '08 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

US3512082

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:00:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

US3512082

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:00:37

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	31 Mar 2021 20:02:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 20:02:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 20:02:13
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Mar 2021 20:01:53
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:01:53



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:48
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'subject requires self-cath BID'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Mar 2021 20:01:53

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 20:01:53

US3512082

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:00:37

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	26 Apr 2021 18:29:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Apr 2021 18:29:59
Data point term sent to Coder	System	26 Apr 2021 18:28:48
User entered 'urinary tract infection'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'Yes (Y)'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '21 Apr 2021'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 18:27:51

US3512082

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:00:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Apr 2021 18:27:58
User entered 'No (N)' reason for change: Data Entry Error	System	26 Apr 2021 18:27:58
User opened query 'Data is required. Please complete.' (Site from System).	Brenda Anderson (b) (4)	26 Apr 2021 18:27:58
User entered empty.	(b) (4)	
	System	26 Apr 2021 18:27:51
	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '26 Apr 2021'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 18:27:51

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	



US3512082

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:00:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

US3512082

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:00:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

US3512082

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:00:37

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '1'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	



**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	26 Apr 2021 18:27:51
	(b) (4)	

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Apr 2021 18:27:51

**US3512082**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 18:27:51

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:00:37

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:13
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:17:24
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:11:38

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:23:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:23:13
Data point term sent to Coder	System	15 Aug 2020 00:12:44
User entered 'aspirin'	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:12:28



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:12:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'cardioprotective'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:12:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '81'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:12:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:12:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:12:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'once daily (QD)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:12:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:12:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:12:28



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:12:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:28:34
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).	Taylor Johnson (b) (4)	15 Aug 2020 00:12:44
	(b) (4)	
User entered 'un UNK 2008'	System	15 Aug 2020 00:12:28
	Taylor Johnson (b) (4)	15 Aug 2020 00:12:28
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:12:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 16:14:40
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 16:14:40
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 16:14:40
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	15 Aug 2020 00:12:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 16:14:40
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 16:14:40
User entered '03 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 16:14:40
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Taylor Johnson (b) (4)	15 Aug 2020 00:12:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Aug 2020 00:12:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 00:12:49
User entered 'No (N)' reason for change: Data Entry Error	Taylor Johnson (b) (4)	15 Aug 2020 00:12:49
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Aug 2020 00:12:28
User entered empty.	System	15 Aug 2020 00:12:28
	Taylor Johnson (b) (4)	15 Aug 2020 00:12:28
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
User entered '1'	System	15 Aug 2020 00:12:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
User entered '1'	System	15 Aug 2020 00:12:28



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:27:30
User entered '804 (804)'	System	15 Aug 2020 00:12:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 06:37:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 06:37:14
Data point term sent to Coder	System	15 Aug 2020 00:14:45
User entered 'Pantoprazole'	Taylor Johnson (b) (4)	15 Aug 2020 00:13:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:37

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	15 Aug 2020 00:13:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'preventative due to aspirin use'	Taylor Johnson (b) (4)	15 Aug 2020 00:13:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '40'	Taylor Johnson (b) (4)	15 Aug 2020 00:13:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	Taylor Johnson (b) (4)	15 Aug 2020 00:13:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:13:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'once daily (QD)'	Taylor Johnson (b) (4)	15 Aug 2020 00:13:47



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:13:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4)	15 Aug 2020 00:13:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:13:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:28:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Taylor Johnson (b) (4)	15 Aug 2020 00:13:57
User entered 'un UNK 2008'	(b) (4)	
	System	15 Aug 2020 00:13:47
	Taylor Johnson (b) (4)	15 Aug 2020 00:13:47
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:13:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	15 Aug 2020 00:13:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:37**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:13:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Aug 2020 00:14:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Aug 2020 00:14:31
User entered 'No (N)' reason for change: Data Entry Error	Taylor Johnson (b) (4)	15 Aug 2020 00:14:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Aug 2020 00:13:47
User entered empty.	System	15 Aug 2020 00:13:47
	Taylor Johnson (b) (4)	15 Aug 2020 00:13:47
	(b) (4)	



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 00:13:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 00:13:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 00:13:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	15 Aug 2020 00:23:14
User coded data point as Term Coded data point by	Coder Import (b) (4)	15 Aug 2020 00:23:14
User: Coder System - version WHODrug-Global-B3\\202003.	System	15 Aug 2020 00:15:46
Data point term sent to Coder	Taylor Johnson (b) (4)	15 Aug 2020 00:15:09
User entered 'Atorvastatin'	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:15:09

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'hypercholesterolemia'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:15:09

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '80'	Taylor Johnson (b) (4)	15 Aug 2020 00:15:09

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:15:09



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:15:09

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'once daily (QD)'	Taylor Johnson (b) (4)	15 Aug 2020 00:15:09

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:15:09

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4)	15 Aug 2020 00:15:09

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:15:09

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:28:42
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).	Taylor Johnson (b) (4)	15 Aug 2020 00:53:14
User entered 'un UNK 2008'	(b) (4)	
	System	15 Aug 2020 00:15:09
	Taylor Johnson (b) (4)	15 Aug 2020 00:15:09
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:15:09

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:15:09



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:15:09

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:15:09

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 00:15:09

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 00:15:09

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 00:15:09

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Aug 2020 00:23:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:23:14
Data point term sent to Coder	System	15 Aug 2020 00:17:49
User entered 'Lisinopril'	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:17:35

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:17:35

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 08:19:51
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'added to mh' (Site from DM).	Brenda Anderson (b) (4) (b) (4)	08 Oct 2020 17:51:38
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:29:27
User entered 'hypertension'	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:17:35



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '10'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:17:35

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:17:35

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:17:35

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'once daily (QD)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:17:35

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:17:35

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:17:35

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:17:35

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:28:46
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).	Taylor Johnson (b) (4)	15 Aug 2020 00:53:05
User entered 'un UNK 2008'	(b) (4)	
	System	15 Aug 2020 00:17:35
	Taylor Johnson (b) (4)	15 Aug 2020 00:17:35
	(b) (4)	



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:17:35

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	04 Dec 2020 15:33:35
User entered 'Yes (Y)'	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:17:35

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	04 Dec 2020 15:33:35
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	04 Dec 2020 15:33:29
User entered '27 Nov 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	04 Dec 2020 15:33:29
User entered empty.	(b) (4)	
	Taylor Johnson (b) (4)	15 Aug 2020 00:17:35
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:17:35

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
User entered '1'	System	15 Aug 2020 00:17:35

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
User entered '1'	System	15 Aug 2020 00:17:35

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:11
User entered '804 (804)'	System	15 Aug 2020 00:17:35

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: PRASUGREL HYDROCHLORIDE, PRODUCTSYNONYM: EFFIENT - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 08:54:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 08:54:31
Data point term sent to Coder	System	29 Mar 2021 18:37:49
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 18:37:30
Coding entries removed.	(b) (4), (b) (6)	29 Mar 2021 18:37:30
Signature has been broken.	(b) (4), (b) (6)	29 Mar 2021 18:37:30
User entered 'PRASUGREL (Effient)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 18:37:30
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: PRASUGREL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Aug 2020 06:33:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Aug 2020 06:33:13
Data point term sent to Coder	System	15 Aug 2020 00:18:49
User entered 'Prasugrel'	Taylor Johnson (b) (4)	15 Aug 2020 00:18:28

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**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:18:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'coronary artery disease'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:18:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '10'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:18:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:18:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:18:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'once daily (QD)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:18:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:18:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:18:28



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:18:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (DEC2019). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 08:20:25
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (DEC2019). Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'Correct date entered; MH updated.' (Site from DM).	Allison Crain (b) (4) (b) (4)	09 Oct 2020 18:09:02
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (DEC2019). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:30:57
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)	16 Aug 2020 14:28:50
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 'data entered per protocol' (Site from System).	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:53:23
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	15 Aug 2020 00:18:28
User entered 'un UNK 2015'	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:18:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:18:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 16:12:29
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 16:12:29
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 16:12:29
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	15 Aug 2020 00:18:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 16:12:29
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 16:12:29
User entered '03 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 16:12:29
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Taylor Johnson (b) (4)	15 Aug 2020 00:18:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:18:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
User entered '1'	System	15 Aug 2020 00:18:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
User entered '1'	System	15 Aug 2020 00:18:28



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:45:17
User entered '804 (804)'	System	15 Aug 2020 00:18:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: CHEMOTHERAPEUTICS FOR TOPICAL USE, ATC: OTHER CHEMOTHERAPEUTICS, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 08:36:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 08:36:10
Data point term sent to Coder	System	15 Aug 2020 00:30:57
User entered 'metronidazole 1%'	Taylor Johnson (b) (4)	15 Aug 2020 00:30:46

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:37

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:30:46

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'rosacea'	Taylor Johnson (b) (4)	15 Aug 2020 00:30:46

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'I'	Taylor Johnson (b) (4)	15 Aug 2020 00:30:46

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Other (OTHER)'	Taylor Johnson (b) (4)	15 Aug 2020 00:30:46

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'application'	Taylor Johnson (b) (4)	15 Aug 2020 00:30:46

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'once daily (QD)'	Taylor Johnson (b) (4)	15 Aug 2020 00:30:46



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:30:46

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Topical (TOPICAL)'	Taylor Johnson (b) (4)	15 Aug 2020 00:30:46

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:30:46

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:28:54
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).	Taylor Johnson (b) (4)	15 Aug 2020 00:53:32
User entered 'un UNK 2006'	(b) (4)	
	System	15 Aug 2020 00:30:46
	Taylor Johnson (b) (4)	15 Aug 2020 00:30:46
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:30:46

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	15 Aug 2020 00:30:46

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:30:46

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:30:46



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 00:30:46

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 00:30:46

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 00:30:46

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:37:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:37:09
Data point term sent to Coder	System	15 Aug 2020 00:35:59
User entered 'vitamin b12'	Taylor Johnson (b) (4)	15 Aug 2020 00:35:04

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:35:04

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'vitamin b12 deficiency'	Taylor Johnson (b) (4)	15 Aug 2020 00:35:04

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '2500'	Taylor Johnson (b) (4)	15 Aug 2020 00:35:04

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	Taylor Johnson (b) (4)	15 Aug 2020 00:35:04



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:35:04

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'once daily (QD)'	Taylor Johnson (b) (4)	15 Aug 2020 00:35:04

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:35:04

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4)	15 Aug 2020 00:35:04

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:35:04

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:28:58
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).	Taylor Johnson (b) (4)	15 Aug 2020 00:35:22
User entered 'un UNK 2018'	(b) (4)	
	System	15 Aug 2020 00:35:04
	Taylor Johnson (b) (4)	15 Aug 2020 00:35:04
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Taylor Johnson (b) (4)	15 Aug 2020 00:35:04

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:35:04



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:35:04

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:35:04

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 00:35:04

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 00:35:04

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 00:35:04

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: FLUOCINOLONE ACETONIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 10:16:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 10:16:08
Data point term sent to Coder	System	15 Aug 2020 00:40:59
User entered 'fluocinolone acetonide 0.01%'	Taylor Johnson (b) (4)	15 Aug 2020 00:40:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:40:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'rash in ear canals'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:40:16



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'I'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:40:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Other (OTHER)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:40:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'application'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:40:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'as needed (PRN)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:40:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:40:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Other (OTHER)'	Taylor Johnson (b) (4)	15 Aug 2020 00:40:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'intraotic'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:40:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:29:02
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).	Taylor Johnson (b) (4)	15 Aug 2020 00:53:42
User entered 'un UNK 2019'	(b) (4)	
	System	15 Aug 2020 00:40:16
	Taylor Johnson (b) (4)	15 Aug 2020 00:40:16
	(b) (4)	



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:40:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	15 Aug 2020 00:40:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:40:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:40:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:40:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:40:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:40:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:43:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:43:07
Data point term sent to Coder	System	15 Aug 2020 00:42:00
User entered 'fexofenadine'	Taylor Johnson (b) (4)	15 Aug 2020 00:41:47



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:37

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:41:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'seasonal allergies'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:41:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '180'	Taylor Johnson (b) (4)	15 Aug 2020 00:41:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	Taylor Johnson (b) (4)	15 Aug 2020 00:41:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:41:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'once daily (QD)'	Taylor Johnson (b) (4)	15 Aug 2020 00:41:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:41:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	Taylor Johnson (b) (4)	15 Aug 2020 00:41:47



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:41:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:29:06
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Taylor Johnson (b) (4)	15 Aug 2020 00:41:59
User entered 'un UNK 2010'	(b) (4)	
	System	15 Aug 2020 00:41:47
	Taylor Johnson (b) (4)	15 Aug 2020 00:41:47
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Taylor Johnson (b) (4)	15 Aug 2020 00:41:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	15 Aug 2020 00:41:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:41:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:41:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 00:41:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 00:41:47



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 00:41:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 19:00:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 19:00:29
Data point term sent to Coder Coding entries removed.	System Allison Crain (b) (4)	09 Oct 2020 18:10:41 09 Oct 2020 18:10:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 00:13:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 00:13:19
Data point term sent to Coder User entered 'docusate calcium'	System Taylor Johnson (b) (4)	15 Aug 2020 00:44:01 15 Aug 2020 00:43:31

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:37

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:43:31

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:13:33
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'added to medical history' (Site from DM).	Brenda Anderson (b) (4)	20 Nov 2020 13:44:15
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:57:04
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the preventive indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 08:20:48
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the preventive indication. Update Con Med eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Allison Crain (b) (4)	09 Oct 2020 18:10:15
User entered 'CONSTIPATION' reason for change: Data Entry Error	Allison Crain (b) (4)	09 Oct 2020 18:10:05
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the preventive indication. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 07:32:06
User entered 'preventative'	Taylor Johnson (b) (4)	15 Aug 2020 00:43:31

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '240'	Taylor Johnson (b) (4)	15 Aug 2020 00:43:31

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:43:31

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:43:31

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'every other day (QOD)'	Taylor Johnson (b) (4)	15 Aug 2020 00:43:31



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:43:31

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:43:31

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:43:31

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:29:10
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).	Taylor Johnson (b) (4)	15 Aug 2020 00:53:52
User entered 'un UNK 2007'	(b) (4)	
	System	15 Aug 2020 00:43:31
	Taylor Johnson (b) (4)	15 Aug 2020 00:43:31
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:43:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	15 Aug 2020 00:43:31

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:43:31

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:43:31



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Aug 2020 00:43:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Aug 2020 00:43:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 00:43:31

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:37

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Aug 2020 10:06:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	16 Aug 2020 10:06:07
Data point term sent to Coder	System	15 Aug 2020 00:46:02
User entered 'Diclofenac 1%'	Taylor Johnson (b) (4)	15 Aug 2020 00:45:17

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:37

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:45:17

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'back pain'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:45:17

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'I'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:45:17

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Other (OTHER)'	Taylor Johnson (b) (4)	15 Aug 2020 00:45:17



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'application'	Taylor Johnson (b) (4)	15 Aug 2020 00:45:17

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'as needed (PRN)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:45:17

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:45:17

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Topical (TOPICAL)'	Taylor Johnson (b) (4)	15 Aug 2020 00:45:17

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:45:17

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:29:14
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Taylor Johnson (b) (4)	15 Aug 2020 00:54:04
User entered 'un UNK 2017'	(b) (4)	
	System	15 Aug 2020 00:45:17
	Taylor Johnson (b) (4)	15 Aug 2020 00:45:17
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Taylor Johnson (b) (4)	15 Aug 2020 00:45:17

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	15 Aug 2020 00:45:17



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	15 Aug 2020 00:54:29
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	15 Aug 2020 00:54:29
User entered empty; reason for change Data Entry Error	Taylor Johnson (b) (4)	15 Aug 2020 00:54:29
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	15 Aug 2020 00:45:17
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	15 Aug 2020 00:45:17
User entered 'un UNK 2010'	Taylor Johnson (b) (4)	15 Aug 2020 00:45:17

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:45:17

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:45:17

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:45:17

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:45:17

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:48:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:48:09
Data point term sent to Coder	System	15 Aug 2020 00:47:04
User entered 'Acetaminophen'	Taylor Johnson (b) (4)	15 Aug 2020 00:46:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:37

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:46:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'back pain'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:46:26



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '500'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:46:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:46:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:46:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'as needed (PRN)'	Taylor Johnson (b) (4)	15 Aug 2020 00:46:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:46:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:46:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:46:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:29:18
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).	Taylor Johnson (b) (4)	15 Aug 2020 00:54:38
User entered 'un UNK 2010'	(b) (4)	
	System	15 Aug 2020 00:46:26
	Taylor Johnson (b) (4)	15 Aug 2020 00:46:26
	(b) (4)	



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:46:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	15 Aug 2020 00:46:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:46:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:46:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:46:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:46:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:46:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:49:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:49:10
Data point term sent to Coder	System	15 Aug 2020 00:48:05
User entered 'fluticasone'	Taylor Johnson (b) (4)	15 Aug 2020 00:47:47



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:47:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'seasonal allergies'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:47:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '50'	Taylor Johnson (b) (4)	15 Aug 2020 00:47:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'ug (ug)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:47:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:47:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'as needed (PRN)'	Taylor Johnson (b) (4)	15 Aug 2020 00:47:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:47:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Nasal (NASAL)'	Taylor Johnson (b) (4)	15 Aug 2020 00:47:47



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:47:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:29:22
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).	Taylor Johnson (b) (4)	15 Aug 2020 00:54:46
User entered 'un UNK 2019'	(b) (4)	
	System	15 Aug 2020 00:47:47
	Taylor Johnson (b) (4)	15 Aug 2020 00:47:47
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:47:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:47:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:47:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:47:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:47:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:47:47



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:47:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: ANTIALLERGIC AGENTS, EXCL. CORTICOSTEROIDS, PRODUCT: AZELASTINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 05:44:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 05:44:09
Data point term sent to Coder	System	15 Aug 2020 00:50:07
User entered 'azelastine hydrochloride 0.1%'	Taylor Johnson (b) (4)	15 Aug 2020 00:49:56

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:49:56

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'seasonal allergies'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:49:56

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'I'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:49:56

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'puff (PUFF)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:49:56

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:49:56

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'as needed (PRN)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:49:56



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:49:56

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Nasal (NASAL)'	Taylor Johnson (b) (4)	15 Aug 2020 00:49:56

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:49:56

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:29:26
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).	Taylor Johnson (b) (4)	15 Aug 2020 00:50:08
User entered 'un UNK 2019'	(b) (4)	
	System	15 Aug 2020 00:49:56
	Taylor Johnson (b) (4)	15 Aug 2020 00:49:56
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:49:56

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	15 Aug 2020 00:49:56

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:49:56

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:49:56



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:49:56

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:49:56

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:49:56

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: SENSORY ORGANS, ATC: OTOLOGICALS, ATC: CORTICOSTEROIDS, ATC: CORTICOSTEROIDS, PRODUCT: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 01:48:23
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 01:48:23
Data point term sent to Coder	System	15 Aug 2020 00:52:13
User entered 'hydrocortisone 1%'	Taylor Johnson (b) (4) (b) (4)	15 Aug 2020 00:51:38

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:00:37

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:51:38

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'rash in ear canals'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:51:38

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'I'	Taylor Johnson (b) (4)	15 Aug 2020 00:51:38

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Other (OTHER)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:51:38



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'application'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:51:38

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'as needed (PRN)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:51:38

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:51:38

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Other (OTHER)'	Taylor Johnson (b) (4)	15 Aug 2020 00:51:38

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'external auditory canals'	Taylor Johnson (b) (4)	15 Aug 2020 00:51:38

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:29:29
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).	Taylor Johnson (b) (4)	15 Aug 2020 00:54:57
User entered 'un UNK 2000'	(b) (4)	
	System	15 Aug 2020 00:51:38
	Taylor Johnson (b) (4)	15 Aug 2020 00:51:38
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Taylor Johnson (b) (4)	15 Aug 2020 00:51:38

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	15 Aug 2020 00:51:38



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:51:38

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:51:38

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:51:38

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:51:38

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:51:38

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:54:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 00:54:13
Data point term sent to Coder	System	15 Aug 2020 00:53:14
User entered 'Tadalafil'	Taylor Johnson (b) (4)	15 Aug 2020 00:52:42

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Taylor Johnson (b) (4)	15 Aug 2020 00:52:42

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'erectile dysfunction'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:52:42



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '20'	Taylor Johnson (b) (4)	15 Aug 2020 00:52:42

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	Taylor Johnson (b) (4)	15 Aug 2020 00:52:42

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:52:42

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'as needed (PRN)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:52:42

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:52:42

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:52:42

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:52:42

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
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)	
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 'data entered per protocol' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 14:29:34
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).	Taylor Johnson (b) (4)	15 Aug 2020 00:52:56
User entered 'un UNK 2019'	(b) (4)	
	System	15 Aug 2020 00:52:42
	Taylor Johnson (b) (4)	15 Aug 2020 00:52:42
	(b) (4)	



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:00:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:52:42

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Taylor Johnson (b) (4)	15 Aug 2020 00:52:42

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:52:42

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Taylor Johnson (b) (4)	15 Aug 2020 00:52:42

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:52:42

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:52:42

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 00:52:42

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Oct 2020 07:41:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 07:41:23
Data point term sent to Coder	System	20 Oct 2020 17:03:00
User entered 'methylprednisolone succinate'	Sheldon Warren (b) (4) (b) (4)	20 Oct 2020 17:02:44



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	20 Oct 2020 17:02:44

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'exercise worsened back muscle spasms'	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:02:44

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '125'	(b) (4) Sheldon Warren (b) (4) (b) (4)	20 Oct 2020 17:02:44

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	20 Oct 2020 17:02:44

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	20 Oct 2020 17:02:44

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'once (ONCE)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	20 Oct 2020 17:02:44

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	20 Oct 2020 17:02:44

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:02:44



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	20 Oct 2020 17:02:44

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '19 Oct 2020'	(b) (4) Sheldon Warren (b) (4) (b) (4)	20 Oct 2020 17:02:44

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	20 Oct 2020 17:02:44

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:02:44

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '19 Oct 2020'	(b) (4) Sheldon Warren (b) (4) (b) (4)	20 Oct 2020 17:02:44

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	20 Oct 2020 17:02:44

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
User entered empty.	System	20 Oct 2020 17:02:44

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
User entered empty.	System	20 Oct 2020 17:02:44



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:34:26
User entered empty.	System	20 Oct 2020 17:02:44

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 17:05:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 17:05:46
Data point term sent to Coder User entered 'robaxin'	System Sheldon Warren (b) (4)	20 Oct 2020 17:05:02 20 Oct 2020 17:04:08

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:00:37

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:04:08

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'back muscle spasms'	Sheldon Warren (b) (4)	20 Oct 2020 17:04:08

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '750'	Sheldon Warren (b) (4)	20 Oct 2020 17:04:08

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	Sheldon Warren (b) (4)	20 Oct 2020 17:04:08

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:04:08

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'three times daily (TID)'	Sheldon Warren (b) (4)	20 Oct 2020 17:04:08



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	20 Oct 2020 17:04:08

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	Sheldon Warren (b) (4)	20 Oct 2020 17:04:08

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	20 Oct 2020 17:04:08

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '20 Oct 2020'	Sheldon Warren (b) (4)	20 Oct 2020 17:04:08

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:00:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	20 Oct 2020 17:04:08

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	20 Oct 2020 17:04:08

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	20 Oct 2020 17:04:08

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Sheldon Warren (b) (4)	20 Oct 2020 17:04:08



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Oct 2020 17:04:08

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 17:04:08

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 17:04:08

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:00:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: ERYTHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Nov 2020 03:55:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 03:55:42
Data point term sent to Coder	System	09 Nov 2020 19:38:38
User entered 'erythromycin .5%'	Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:38:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:38:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 07:01:50
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'data confirmed as is' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	27 Jan 2021 13:14:55
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:00:28
User entered 'Right hordeolum'	Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:38:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'l'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:38:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Other (OTHER)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:38:16



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:00:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'application'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:38:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'as needed (PRN)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:38:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:38:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Topical (TOPICAL)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:38:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:00:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:38:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '30 Oct 2020'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:38:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:38:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:00:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	04 Dec 2020 15:34:24
	(b) (4)	
	Sheldon Warren (b) (4)	09 Nov 2020 19:38:16
	(b) (4)	



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	04 Dec 2020 15:34:24
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	04 Dec 2020 15:34:20
User entered '11 Nov 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	04 Dec 2020 15:34:20
User entered empty.	(b) (4)	
	Sheldon Warren (b) (4)	09 Nov 2020 19:38:16
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:38:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
User entered empty.	System	09 Nov 2020 19:38:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
User entered empty.	System	09 Nov 2020 19:38:16

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:31
User entered empty.	System	09 Nov 2020 19:38:16

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: ERYTHROMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Nov 2020 03:56:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 03:56:41
Data point term sent to Coder	System	09 Nov 2020 19:39:40
User entered 'erythromycin .5%'	Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:39:27

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:39:27

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Left Hordeolum'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:39:27



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'l'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:39:27

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Other (OTHER)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:39:27

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:00:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'application'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:39:27

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'as needed (PRN)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:39:27

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:39:27

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Topical (TOPICAL)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:39:27

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:00:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:39:27

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '4 Nov 2020'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:39:27



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:00:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:39:27

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:00:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	04 Dec 2020 15:36:38
	(b) (4)	
	Sheldon Warren (b) (4)	09 Nov 2020 19:39:27
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'data confirmed as is' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 07:01:21
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'data confirmed as is' (Site from DM).	Taylor Johnson (b) (4)	27 Jan 2021 13:15:13
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:00:47
User entered '11 Nov 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	04 Dec 2020 15:36:38
User entered empty.	(b) (4)	
	Sheldon Warren (b) (4)	09 Nov 2020 19:39:27
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:39:27

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
User entered empty.	System	09 Nov 2020 19:39:27

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
User entered empty.	System	09 Nov 2020 19:39:27

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:03:39
User entered empty.	System	09 Nov 2020 19:39:27

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:00:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CARMELLOSE SODIUM, PRODUCTSYNONYM: CARBOXYMETHYLCELLULOSE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 22:27:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 22:27:17
Data point term sent to Coder	System	04 Dec 2020 15:33:14
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	04 Dec 2020 15:33:11
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'UPDATED' (Site from System).	Allison Crain (b) (4) (b) (4)	04 Dec 2020 15:33:11
User entered 'CARBOXYMETHYLCELLULOSE SODIUM 0.5%' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	04 Dec 2020 15:32:50
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:57:57
Data point term sent to Coder	System	09 Nov 2020 19:41:43
User entered 'Eye drops (.5% eye solution)'	Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:40:55



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:40:55

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Bilateral hordeolum'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:40:55

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'l'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:40:55

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Other (OTHER)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:40:55

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:00:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'drop per eye'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:40:55

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'as needed (PRN)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:40:55

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:40:55

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Intraocular (INTRAOCULAR)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:40:55



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:40:55

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '4 Nov 2020'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:40:55

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:40:55

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:00:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Allison Crain (b) (4)	04 Dec 2020 15:33:47
User entered 'Yes (Y)'	(b) (4)	
	Sheldon Warren (b) (4)	09 Nov 2020 19:40:55
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'data confirmed as is' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 07:09:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'data confirmed as is' (Site from DM).	Taylor Johnson (b) (4)	27 Jan 2021 13:16:10
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:01:05
User closed query 'Ongoing is Yes, however End dateSystem is provided. Please correct.' (Site from System).		04 Dec 2020 15:33:47
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	04 Dec 2020 15:33:05
User entered '11 Nov 2020' reason for change: Data Entry Error	Allison Crain (b) (4)	04 Dec 2020 15:33:05
User entered empty.	(b) (4)	
	Sheldon Warren (b) (4)	09 Nov 2020 19:40:55
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:40:55

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
User entered empty.	System	09 Nov 2020 19:40:55

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
User entered empty.	System	09 Nov 2020 19:40:55



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:31:04
User entered empty.	System	09 Nov 2020 19:40:55

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:00:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Jan 2021 15:25:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Jan 2021 15:25:19
Data point term sent to Coder	System	27 Jan 2021 13:28:33
Coding entries removed.	Taylor Johnson (b) (4)	27 Jan 2021 13:28:08
User entered 'AUGMENTIN (amoxicillin / clavulanic acid)' reason for change: Data Entry Error	Taylor Johnson (b) (4)	27 Jan 2021 13:28:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 03:37:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Nov 2020 03:37:43
Data point term sent to Coder	System	09 Nov 2020 19:42:44
User entered 'augmentin'	Sheldon Warren (b) (4)	09 Nov 2020 19:41:48

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:41:48

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'bilateral hordeolum'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:41:48

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 875mg/125mg).' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 06:19:46
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 875mg/125mg).' answered with 'data updated' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	27 Jan 2021 13:28:21
User entered '875/ 125' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	27 Jan 2021 13:28:08
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 875mg/125mg).' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 10:59:24
User entered '875'	Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:41:48

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:41:48

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:00:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:41:48

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'twice daily (BID)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:41:48



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:41:48

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	(b) (4) Sheldon Warren (b) (4)	09 Nov 2020 19:41:48

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:00:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:41:48

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '4 Nov 2020'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:41:48

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:41:48

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:00:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered 'Yes (Y)'	Allison Crain (b) (4)	04 Dec 2020 15:36:59
	(b) (4)	
	Sheldon Warren (b) (4)	09 Nov 2020 19:41:48
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query ' Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 07:14:32
Query ' Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'data confirmed as is' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	27 Jan 2021 13:29:00
User opened query ' Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 10:59:38
User entered '11 Nov 2020' reason for change: Data Entry Error	Allison Crain (b) (4) (b) (4)	04 Dec 2020 15:36:59
User entered empty.	Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:41:48

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	09 Nov 2020 19:41:48



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
User entered '2'	System	09 Nov 2020 19:41:48

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
User entered '1'	System	09 Nov 2020 19:41:48

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:25
User entered '804 (804)'	System	09 Nov 2020 19:41:48

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:00:37

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User closed query 'Per DM CLR: this Con Med had dose increased on 28 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medication's dosage. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 04:16:33
Query 'Per DM CLR: this Con Med had dose increased on 28 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medication's dosage. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'Not due to a worsening, just for better control per pt.' (Site from DM).	Allison Crain (b) (4) (b) (4)	05 Mar 2021 15:51:04
User opened query 'Per DM CLR: this Con Med had dose increased on 28 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medication's dosage. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 01:50:03
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 15:39:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Dec 2020 15:39:58
Data point term sent to Coder	System	04 Dec 2020 15:38:18
User entered 'LISINOPRIL'	Allison Crain (b) (4) (b) (4)	04 Dec 2020 15:37:50

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Allison Crain (b) (4)	04 Dec 2020 15:37:50

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'HYPERTENSION'	Allison Crain (b) (4)	04 Dec 2020 15:37:50

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '20'	Allison Crain (b) (4)	04 Dec 2020 15:37:50

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	Allison Crain (b) (4)	04 Dec 2020 15:37:50



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Allison Crain (b) (4)	04 Dec 2020 15:37:50

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'once daily (QD)'	Allison Crain (b) (4)	04 Dec 2020 15:37:50

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:00:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Allison Crain (b) (4) (b) (4)	04 Dec 2020 15:37:50

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	Allison Crain (b) (4)	04 Dec 2020 15:37:50

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Allison Crain (b) (4)	04 Dec 2020 15:37:50

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with LISINOPRIL, #4 / (Start date UN UNK 2008 - Stop date 27 NOV 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 06:20:28
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with LISINOPRIL, #4 / (Start date UN UNK 2008 - Stop date 27 NOV 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'data updated' (Site from DM).	Taylor Johnson (b) (4) (b) (4)	27 Jan 2021 13:29:57
User entered '28 Nov 2020' reason for change: Data Entry Error	Taylor Johnson (b) (4) (b) (4)	27 Jan 2021 13:29:49
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with LISINOPRIL, #4 / (Start date UN UNK 2008 - Stop date 27 NOV 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 09:14:26
User entered '27 Nov 2020'	Allison Crain (b) (4) (b) (4)	04 Dec 2020 15:37:50

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:00:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Allison Crain (b) (4)	04 Dec 2020 15:37:50

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Allison Crain (b) (4)	04 Dec 2020 15:37:50



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Allison Crain (b) (4)	04 Dec 2020 15:37:50

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Allison Crain (b) (4)	04 Dec 2020 15:37:50

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:37:50

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 15:37:50

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Dec 2020 15:37:50

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 21:37:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Dec 2020 21:37:58
Data point term sent to Coder	System	11 Dec 2020 21:36:47
User entered 'Shingles vaccine'	Sheldon Warren (b) (4)	11 Dec 2020 21:36:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:00:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Dec 2020 21:36:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'shingles prophylaxis'	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Dec 2020 21:36:28



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:00:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'l'	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Dec 2020 21:36:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Other (OTHER)'	Sheldon Warren (b) (4)	11 Dec 2020 21:36:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:00:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'injection'	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Dec 2020 21:36:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:00:37**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'once (ONCE)'	(b) (4) Sheldon Warren (b) (4)	11 Dec 2020 21:36:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:00:37**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Dec 2020 21:36:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:00:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Sheldon Warren (b) (4)	11 Dec 2020 21:36:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:00:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Dec 2020 21:36:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '10 Dec 2020'	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Dec 2020 21:36:28



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Dec 2020 21:36:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Dec 2020 21:36:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:00:37**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '10 Dec 2020'	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Dec 2020 21:36:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	11 Dec 2020 21:36:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
User entered empty.	System	11 Dec 2020 21:36:28

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
User entered empty.	System	11 Dec 2020 21:36:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 08:00:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:49:35
User entered empty.	System	11 Dec 2020 21:36:28

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:00:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM DS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 16:02:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 16:02:52
Data point term sent to Coder	System	16 Mar 2021 16:02:15
DataPoint Un-verified.	(b) (4), (b) (6)	16 Mar 2021 16:01:29
Coding entries removed.	(b) (4), (b) (6)	16 Mar 2021 16:01:29
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 16:01:29
User entered 'BACTRIM DS' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 16:01:29
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 21:06:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 21:06:39

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EAB) (1725)

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**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	10 Feb 2021 21:06:14
User entered 'bactrin'	Brenda Anderson (b) (4)	10 Feb 2021 21:05:31
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	10 Feb 2021 21:05:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'acute urinary retention'	(b) (4) Brenda Anderson (b) (4)	10 Feb 2021 21:05:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '400-80'	(b) (4) Brenda Anderson (b) (4)	10 Feb 2021 21:05:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	(b) (4) Brenda Anderson (b) (4)	10 Feb 2021 21:05:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Brenda Anderson (b) (4)	10 Feb 2021 21:05:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'twice daily (BID)'	(b) (4) Brenda Anderson (b) (4)	10 Feb 2021 21:05:31

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Brenda Anderson (b) (4) (b) (4)	10 Feb 2021 21:05:31



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	(b) (4) Brenda Anderson (b) (4)	10 Feb 2021 21:05:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Brenda Anderson (b) (4)	10 Feb 2021 21:05:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '26 Jan 2021'	(b) (4) Brenda Anderson (b) (4)	(b) (4) 10 Feb 2021 21:05:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	(b) (4) Brenda Anderson (b) (4)	10 Feb 2021 21:05:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	10 Feb 2021 21:05:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '2 Feb 2021'	(b) (4) Brenda Anderson (b) (4)	10 Feb 2021 21:05:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	10 Feb 2021 21:05:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
User entered '2'	System	10 Feb 2021 21:05:31



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
User entered '1'	System	10 Feb 2021 21:05:31

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:29:52
User entered '804 (804)'	System	10 Feb 2021 21:05:31

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:00:37

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: OTHER UROLOGICALS, PRODUCT: PHENAZOPYRIDINE HYDROCHLORIDE, PRODUCTSYNONYM: PYRIDIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 08:44:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 08:44:35
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4) (b) (4)	12 Feb 2021 20:48:27
Data point term sent to Coder	System	10 Feb 2021 21:16:19
User entered 'pyridium oral'	Sheldon Warren (b) (4) (b) (4)	10 Feb 2021 21:16:19

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	Sheldon Warren (b) (4)	10 Feb 2021 21:16:19

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'acute urinary retention'	Sheldon Warren (b) (4)	10 Feb 2021 21:16:19

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '100'	Sheldon Warren (b) (4)	10 Feb 2021 21:16:19

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'mg (mg)'	Sheldon Warren (b) (4)	10 Feb 2021 21:16:19

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	10 Feb 2021 21:16:19



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'as needed (PRN)'	Sheldon Warren (b) (4)	10 Feb 2021 21:16:19

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	(b) (4) Sheldon Warren (b) (4)	10 Feb 2021 21:16:19

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Oral (ORAL)'	Sheldon Warren (b) (4)	10 Feb 2021 21:16:19

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	10 Feb 2021 21:16:19

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:00:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '2 Feb 2021'	(b) (4) Sheldon Warren (b) (4)	10 Feb 2021 21:16:19

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '0'	Sheldon Warren (b) (4)	10 Feb 2021 21:16:19

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'Yes (Y)'	Sheldon Warren (b) (4)	10 Feb 2021 21:16:19

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered empty.	Sheldon Warren (b) (4)	10 Feb 2021 21:16:19



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	10 Feb 2021 21:16:19

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 21:16:19

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 21:16:19

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 21:16:19

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
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.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 19:00:47
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 Mar 2021 19:00:47
Data point term sent to Coder	System	12 Mar 2021 18:59:34
User entered 'tylenol'	Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 18:59:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered 'Yes (Y)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 18:59:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered 'Injection reaction prophylaxis'	(b) (4) Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 18:59:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered '1000'	(b) (4) Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 18:59:26



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered 'mg (mg)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 18:59:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 18:59:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered 'once (ONCE)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 18:59:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 18:59:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered 'Oral (ORAL)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 18:59:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered empty.	(b) (4) Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 18:59:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered '3 Mar 2021'	(b) (4) Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 18:59:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered '0'	(b) (4) Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 18:59:26



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 18:59:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered '3 Mar 2021'	(b) (4) Sheldon Warren (b) (4) (b) (4)	12 Mar 2021 18:59:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 21:18:44
User signature succeeded.	Michael Koren (b) (4)	15 Mar 2021 12:45:59
User entered 'No (N)'	(b) (4) Sheldon Warren (b) (4)	12 Mar 2021 18:59:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
User entered empty.	System	12 Mar 2021 18:59:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
User entered empty.	System	12 Mar 2021 18:59:26

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:57:42
User entered empty.	System	12 Mar 2021 18:59:26

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:00:37

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 16:22:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 16:22:52
Data point term sent to Coder	System	16 Mar 2021 16:21:45
User entered 'Aspirin'	(b) (4), (b) (6)	16 Mar 2021 16:20:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 16:20:47



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'Cardioprotective'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered '81'	(b) (4), (b) (6)	16 Mar 2021 16:20:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Mar 2021 16:20:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:00:37**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'every other day (QOD)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:00:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:00:37

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:47



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 16:20:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:00:37**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 16:20:47

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:20:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 16:20:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Mar 2021 16:20:47

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Mar 2021 16:20:47



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN, PRODUCTSYNONYM: MACRODANTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 13:51:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 13:51:32
Data point term sent to Coder	System	19 Mar 2021 13:50:11
User entered 'Macrodantin'	Brenda Anderson (b) (4)	19 Mar 2021 13:49:52

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	19 Mar 2021 13:49:52
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'ESCHERICHIA COLI INFECTION'	(b) (4) Brenda Anderson (b) (4)	19 Mar 2021 13:49:52

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered '100'	(b) (4) Brenda Anderson (b) (4) (b) (4)	19 Mar 2021 13:49:52

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'mg (mg)'	(b) (4) Brenda Anderson (b) (4)	19 Mar 2021 13:49:52

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:00:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered empty.	(b) (4) Brenda Anderson (b) (4)	19 Mar 2021 13:49:52
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'twice daily (BID)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	19 Mar 2021 13:49:52

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered empty.	(b) (4) Brenda Anderson (b) (4)	19 Mar 2021 13:49:52
	(b) (4)	



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'Oral (ORAL)'	(b) (4) Brenda Anderson (b) (4)	19 Mar 2021 13:49:52

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:00:37**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered empty.	(b) (4) Brenda Anderson (b) (4)	19 Mar 2021 13:49:52

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered '18 Feb 2021'	(b) (4) Brenda Anderson (b) (4)	19 Mar 2021 13:49:52

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered '0'	(b) (4) Brenda Anderson (b) (4) (b) (4)	19 Mar 2021 13:49:52

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4) (b) (4)	19 Mar 2021 13:49:52

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:00:37**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered '24 Feb 2021'	(b) (4) Brenda Anderson (b) (4)	19 Mar 2021 13:49:52

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 08:00:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:06:08
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'No (N)'	(b) (4) Brenda Anderson (b) (4)	19 Mar 2021 13:49:52

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
User entered '2'	System	19 Mar 2021 13:49:52



**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
User entered '1'	System	19 Mar 2021 13:49:52

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 14:28:24
User entered '804 (804)'	System	19 Mar 2021 13:49:52

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:00:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Apr 2021 18:30:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 18:30:40
Data point term sent to Coder	System	26 Apr 2021 18:30:02
User entered 'Nitrofurantoin'	Brenda Anderson (b) (4) (b) (4)	26 Apr 2021 18:29:43

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'urinary tract infection'	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '100'	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:00:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'mg (mg)'	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	

US3512082

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:00:37**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	



US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:00:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'twice daily (BID)'	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:00:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'Oral (ORAL)'	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	

US3512082

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:00:37**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered empty.	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '21 Apr 2021'	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '0'	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	

US3512082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 08:00:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered '26 Apr 2021'	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	



US3512082

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Koren (b) (4)	28 Apr 2021 21:04:29
	(b) (4)	
User entered 'No (N)'	Brenda Anderson (b) (4)	26 Apr 2021 18:29:43
	(b) (4)	

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 18:29:43

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 18:29:43

**US3512082**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 08:00:37**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Apr 2021 18:29:43

US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:00:37

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:34:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:20:58
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
Signature has been broken.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:19:44
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	16 Mar 2021 15:19:44
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'No (N)'	(b) (4) Allison Crain (b) (4) (b) (4)	09 Oct 2020 18:05:25

US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:00:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:21:05
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:30:21

US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:00:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:21:05
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'Indwelling Catheterization'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:30:21

US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:21:05
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	16 Mar 2021 15:30:21



US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:00:37

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:21:05
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 15:30:21

US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:00:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:21:05
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered '4 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:03:58

US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:00:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:21:05
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'Indwelling Catheterization'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:03:58

US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:21:05
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:03:58

US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:00:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:32:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:21:05
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:03:58

US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:00:37

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:21:05
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:33:09

US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:00:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:21:05
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'Continuous Bladder Lavage'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:33:09

US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:00:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:21:05
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4) System	29 Mar 2021 18:33:20
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	29 Mar 2021 18:33:09
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	29 Mar 2021 18:33:09



US3512082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:00:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:21:05
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 18:33:20
User entered 'Urinary Retention'	(b) (4), (b) (6)	29 Mar 2021 18:33:09

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'USA-US065-2021-MRNA-1273-P301000004'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55



**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Michael'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Koren'	System	11 Feb 2021 17:18:55

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:37

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '4085 University Blvd. South Suite 1'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:37

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Jacksonville'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:37

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Florida'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '32216'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:52:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'US'	(b) (4) System	11 Feb 2021 17:19:28



**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 22:05:49
User entered '4'	System	01 Apr 2021 13:15:11
User entered '3'	System	30 Mar 2021 14:36:00
User entered '2'	System	17 Mar 2021 16:52:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
	(b) (4)	
User entered '1'	System	11 Feb 2021 17:19:28

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'USA-US065-2021-MRNA-1273-P301000004'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55



**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Michael'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Koren'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '4085 University Blvd. South Suite 1'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:37

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Jacksonville'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:37

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Florida'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '32216'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:52:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'US'	(b) (4) System	11 Feb 2021 17:19:28



**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 22:05:49
User entered '4'	System	01 Apr 2021 13:15:11
User entered '3'	System	30 Mar 2021 14:36:00
User entered '2'	System	17 Mar 2021 16:52:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
	(b) (4)	
User entered '1'	System	11 Feb 2021 17:19:28

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 08:00:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered '11/Feb/2021 12:19'	(b) (4) System	11 Feb 2021 17:19:28

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:00:37

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:52:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:28

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'USA-US065-2021-MRNA-1273-P301000004'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55



**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Michael'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Koren'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '4085 University Blvd. South Suite 1'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Jacksonville'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:37

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Florida'	(b) (4), (b) (6)	29 Mar 2021 19:48:29



**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '32216'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:52:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'US'	(b) (4) System	11 Feb 2021 17:19:28

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 22:05:49
User entered '4'	System	01 Apr 2021 13:15:11
User entered '3'	System	30 Mar 2021 14:36:00
User entered '2'	System	17 Mar 2021 16:52:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
	(b) (4)	
User entered '1'	System	11 Feb 2021 17:19:28

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 08:00:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
User entered '17/Mar/2021 12:51'	(b) (4) System	17 Mar 2021 16:52:00

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:00:37

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	19 Mar 2021 20:41:30
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:52:04
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 16:52:00

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'USA-US065-2021-MRNA-1273-P301000004'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55



**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Michael'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Koren'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '4085 University Blvd. South Suite 1'	(b) (4), (b) (6)	29 Mar 2021 19:48:29



US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:37

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Jacksonville'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Florida'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '32216'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:52:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'US'	(b) (4) System	11 Feb 2021 17:19:28

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 22:05:49
User entered '4'	System	01 Apr 2021 13:15:11
User entered '3'	System	30 Mar 2021 14:36:00
User entered '2'	System	17 Mar 2021 16:52:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
	(b) (4)	
User entered '1'	System	11 Feb 2021 17:19:28

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 08:00:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '29/Mar/2021 15:49'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:49:24

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:00:37

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:05:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 14:36:00

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'USA-US065-2021-MRNA-1273-P301000004'	System	11 Feb 2021 17:18:55



**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Michael'	System	11 Feb 2021 17:18:55



**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Koren'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '4085 University Blvd. South Suite 1'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Jacksonville'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:37

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Florida'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '32216'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:52:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'US'	(b) (4) System	11 Feb 2021 17:19:28

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 22:05:49
User entered '4'	System	01 Apr 2021 13:15:11
User entered '3'	System	30 Mar 2021 14:36:00
User entered '2'	System	17 Mar 2021 16:52:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
	(b) (4)	
User entered '1'	System	11 Feb 2021 17:19:28

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 08:00:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered '30/Mar/2021 09:35'	(b) (4) System	30 Mar 2021 14:36:00



US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:00:37

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:05:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
User entered 'I'	(b) (4), (b) (6)	30 Mar 2021 14:36:00

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'USA-US065-2021-MRNA-1273-P301000004'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55



**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Michael'	System	11 Feb 2021 17:18:55

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Koren'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '4085 University Blvd. South Suite 1'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:37

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Jacksonville'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:37

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Florida'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '32216'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:52:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'US'	(b) (4) System	11 Feb 2021 17:19:28



**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 22:05:49
User entered '4'	System	01 Apr 2021 13:15:11
User entered '3'	System	30 Mar 2021 14:36:00
User entered '2'	System	17 Mar 2021 16:52:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
	(b) (4)	
User entered '1'	System	11 Feb 2021 17:19:28

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 08:00:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered '01/Apr/2021 09:15'	(b) (4) System	01 Apr 2021 13:15:11

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:00:37

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 22:05:31
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	02 Apr 2021 19:27:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:15:11

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'USA-US065-2021-MRNA-1273-P301000004'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Yes (Y)'	System	11 Feb 2021 17:18:55



**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'No (N)'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Michael'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 17:19:17
User entered 'Koren'	System	11 Feb 2021 17:18:55

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '4085 University Blvd. South Suite 1'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:37

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Jacksonville'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered 'Florida'	(b) (4), (b) (6)	29 Mar 2021 19:48:29



**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
User signature succeeded.	Michael Koren (b) (4)	31 Mar 2021 17:29:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:35:41
User entered empty.	System	30 Mar 2021 14:31:20
User entered '32216'	(b) (4), (b) (6)	29 Mar 2021 19:48:29

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:05:26
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 16:52:04
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
User entered 'US'	(b) (4) System	11 Feb 2021 17:19:28

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 08:00:37**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	08 Apr 2021 22:05:49
User entered '4'	System	01 Apr 2021 13:15:11
User entered '3'	System	30 Mar 2021 14:36:00
User entered '2'	System	17 Mar 2021 16:52:00
User signature succeeded.	Michael Koren (b) (4)	12 Feb 2021 20:48:27
	(b) (4)	
User entered '1'	System	11 Feb 2021 17:19:28

**US3512082**

**Folder: SAE USA-US065-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 08:00:37**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:57
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:39:32
User entered '08/Apr/2021 18:05'	(b) (4) System	08 Apr 2021 22:05:49

US3512082

Folder: SAE USA-US065-2021-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:00:37

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:14:57
User signature succeeded.	Michael Koren (b) (4)	14 Apr 2021 16:39:32
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 22:05:49