

US3812062 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:53:42

All time stamps listed in this document are displayed in GMT

US3812062

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 19:35:36

Generated On: 10 Jun 2021 09:53:42

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[Participant ID](#)

US3812062

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

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US3812062

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

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

US3812062

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Date of Informed Consent ( <i>dd MMM yyyy</i> )	06 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

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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) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

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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) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

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

US3812062

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	BIPOLAR
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812062

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	VITAMIN D DEFICIENCY
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 (8)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	BILATERAL FIBROCYSTIC BREAST
Start date (dd MMM yyyy)	UN FEB 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)	FEB 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812062

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	HYPOKALEMIA
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	11 JUL 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JUL 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	RIGHT ELBOW BURSITIS
Start date (dd MMM yyyy)	01 MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812062

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	RIGHT ELBOW CELLULITIS
Start date (dd MMM yyyy)	01 MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	01 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	BILATERAL VISION IMPAIRMENT
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	BRAIN ANEURYSM
Start date (dd MMM yyyy)	UN NOV 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN NOV 1998
Stop date completely unknown	False
Start Month and Year (derived)	NOV 1998
Start Year (derived)	1998
Stop Month and Year (derived)	NOV 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	CRANIOTOMY
Start date (dd MMM yyyy)	UN NOV 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN NOV 1998
Stop date completely unknown	False
Start Month and Year (derived)	NOV 1998
Start Year (derived)	1998
Stop Month and Year (derived)	NOV 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	BRAIN ANEURYSM CLIPPING
Start date (dd MMM yyyy)	UN NOV 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN NOV 1998
Stop date completely unknown	False
Start Month and Year (derived)	NOV 1998
Start Year (derived)	1998
Stop Month and Year (derived)	NOV 1998
Stop Year (derived)	1998

US3812062

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	SKULL STEEL PLATE PLACEMENT
Start date (dd MMM yyyy)	UN NOV 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN NOV 1998
Stop date completely unknown	False
Start Month and Year (derived)	NOV 1998
Start Year (derived)	1998
Stop Month and Year (derived)	NOV 1998
Stop Year (derived)	1998

US3812062

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	OCCASIONAL MARIJUANA USE
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812062

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	OSTEOPENIA
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)	_____

US3812062

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	RIGHT ELBOW CELLULITIS
Start date (dd MMM yyyy)	24 JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

US3812062

Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	OSTEOPOROSIS
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)	_____

US3812062

Folder: Screening

Form: Medical History (29)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	ALCOHOL ABUSE
Start date (dd MMM yyyy)	UN UNK 1986
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 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

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Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	CAESAREAN SECTION
Start date (dd MMM yyyy)	21 MAR 1989
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	21 MAR 1989
Stop date completely unknown	False
Start Month and Year (derived)	MAR 1989
Start Year (derived)	1989
Stop Month and Year (derived)	MAR 1989
Stop Year (derived)	1989

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Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Start Year (derived)	1972
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (32)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812062

Folder: Screening

Form: Medical History (33)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	NICOTINE ADDICTION
Start date (dd MMM yyyy)	UN UNK 1983
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 1983
Start Year (derived)	1983
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812062

Folder: Screening

Form: Medical History (34)

Data signed: (b) (4) 16 Apr 2021 14:22:42

Generated On: 10 Jun 2021 09:53:42

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3812062

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	06 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	10:57 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 10:57
Height ( <i>xxx.x</i> )	67.4 in
Weight ( <i>xxx.x</i> )	153.6 lb
BMI ( <i>xxx.x</i> )	23.82217 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 checked="" type="radio"/>
If Other, specify	ND - Not Done
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) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

06 AUG 2020

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

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US3812062

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Date of assessment (dd MMM yyyy) 06 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2017

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

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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 ☒

---

**Specify**

---

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

**No Risk Identified** True

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

US3812062

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

<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)	False
<b>Other</b>	False
<b>Specify</b>	

US3812062

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

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

Visit date (dd MMM yyyy)	06 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3812062

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 101560

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 ☒

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Height	ND - Not Done
Weight	ND - Not Done

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

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)	06 AUG 2020
Time of assessment (00:00-23:59)	10:57 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 10:57
Temperature (xxx.x)	98.1 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

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)	06 AUG 2020
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 13:10
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)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3812062

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

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.*

US3812062

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 06 AUG 2020

What was the treatment time? (00:00-23:59) 12:38 (24 HR)

Treatment Date and Time (derived) 06 AUG 2020 12:38

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

US3812062

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 AUG 2020
Collection time (00:00-23:59)	12:32 (24 HR)
Collection date and time (derived)	06 AUG 2020 12:32

US3812062

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Collection date (dd MMM yyyy)			06 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:35	06 AUG 2020 12:35
Nasopharyngeal Swab 2	No		

US3812062

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

To **TREAT** pain or fever that has already occurred True

To **PREVENT** pain or fever from occurring False

PC Time Stamp 06 AUG 2020 13:23

PC Open Date & Time 06 AUG 2020 12:58

PC Close Date & Time 06 AUG 2020 15:28

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 09:04

PC Open Date & Time

06 AUG 2020 16:23

PC Close Date & Time

07 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.9 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	07 AUG 2020 19:04
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 20:58

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**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

96.5 °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

09 AUG 2020 20:18

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

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**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

97.6 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

10 AUG 2020 19:06

---

PC Open Date & Time

10 AUG 2020 12:00

---

PC Close Date & Time

11 AUG 2020 11:59

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US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**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

97.1 °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

11 AUG 2020 19:08

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

12 AUG 2020 20:34

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 13:24

PC Open Date & Time

06 AUG 2020 12:58

PC Close Date & Time

06 AUG 2020 15:28

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**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

07 AUG 2020 09:05

PC Open Date & Time

06 AUG 2020 16:23

PC Close Date & Time

07 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 19:05

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 20:59

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 20:18

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 19:06

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 19:08

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 20:35

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**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 ☐

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 13:25
PC Open Date & Time	06 AUG 2020 12:58
PC Close Date & Time	06 AUG 2020 15:28

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**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 ☐

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 09:06
PC Open Date & Time	06 AUG 2020 16:23
PC Close Date & Time	07 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**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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US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 19:05
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

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 ☒

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

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

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:19
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

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)

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 19:07
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

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

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

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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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 20:36
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3812062

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812062

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812062

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812062

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

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)	04 SEP 2020
Time of assessment (00:00-23:59)	15:45 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 15:45
Temperature (xxx.x)	98.1 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

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)	04 SEP 2020
Time of assessment (00:00-23:59)	17:31 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 17:31
Temperature (xxx.x)	96.2 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3812062

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

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.*

US3812062

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

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) 04 SEP 2020

What was the treatment time? (00:00-23:59) 16:50 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 16:50

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

US3812062

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 SEP 2020

Collection time (00:00-23:59)

16:15 (24 HR)

Collection date and time (derived)

04 SEP 2020 16:15

US3812062

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:19	04 SEP 2020 16:19
Nasopharyngeal Swab 2	No		

US3812062

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.2 °F

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

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

To **TREAT** pain or fever that has already occurred True

To **PREVENT** pain or fever from occurring False

PC Time Stamp 04 SEP 2020 17:25

PC Open Date & Time 04 SEP 2020 17:10

PC Close Date & Time 04 SEP 2020 19:40

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**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 96.3 °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):

To **TREAT** pain or fever that has already occurred True

To **PREVENT** pain or fever from occurring False

PC Time Stamp 04 SEP 2020 21:47

PC Open Date & Time 04 SEP 2020 20:35

PC Close Date & Time 05 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**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

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

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 06:19

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**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

96.8 °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

08 SEP 2020 09:16

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

08 SEP 2020 20:30

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**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.

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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

10 SEP 2020 05:41

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**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.

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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

10 SEP 2020 16:17

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 17:26

PC Open Date & Time

04 SEP 2020 17:10

PC Close Date & Time

04 SEP 2020 19:40

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**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

04 SEP 2020 21:48

PC Open Date & Time

04 SEP 2020 20:35

PC Close Date & Time

05 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**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

07 SEP 2020 06:20

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**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

08 SEP 2020 09:17

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 20:31

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**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

10 SEP 2020 05:42

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**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

10 SEP 2020 16:18

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**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 ☐

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 17:27
PC Open Date & Time	04 SEP 2020 17:10
PC Close Date & Time	04 SEP 2020 19:40

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**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 ☐

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 21:49
PC Open Date & Time	04 SEP 2020 20:35
PC Close Date & Time	05 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**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 ☐

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

Yes ☐

PC Time stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

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

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**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 ☒

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 09:18
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 20:31
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

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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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 05:43
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**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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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 16:19
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3812062

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812062

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812062

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812062

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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

US3812062

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	01 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	15:22 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 15:22
Temperature ( <i>xxx.x</i> )	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	76 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812062

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

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.*

US3812062

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 OCT 2020
Collection time (00:00-23:59)	15:35 (24 HR)
Collection date and time (derived)	01 OCT 2020 15:35

US3812062

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:51

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 OCT 2020 21:59:25
Patient Cloud Open Date & Time	06 OCT 2020 00:01
Patient Cloud Close Date & Time	10 OCT 2020 23:59

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 OCT 2020 20:57:22
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☒

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 OCT 2020 19:31:41

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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

05 NOV 2020 23:39:43

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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 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	12 NOV 2020 20:48:54
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 21:20:35

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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

28 NOV 2020 12:29:52

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 07:18:10

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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

12 DEC 2020 12:40:53

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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

19 DEC 2020 15:25:25

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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

27 DEC 2020 11:36:57

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 22:43:07

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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

10 JAN 2021 17:52:08

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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20 JAN 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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27 JAN 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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="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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 07:53:17

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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

15 FEB 2021 15:32:24

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 00:17:48

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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

01 MAR 2021 08:37:57

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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

07 MAR 2021 20:43:15

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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

17 MAR 2021 15:22:44

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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

22 MAR 2021 09:41:50

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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

30 MAR 2021 20:34:32

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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 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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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 <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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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10 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 APR 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 12:13:38

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 20:00:51

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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12 MAY 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 292

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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 <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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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="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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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09 JUN 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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="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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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 <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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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30 JUN 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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07 JUL 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

10 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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21 JUL 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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 <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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59
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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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21 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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 <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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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08 SEP 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	18 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	09 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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 <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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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18 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐ 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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JAN 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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12 FEB 2022 00:01

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16 FEB 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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19 FEB 2022 00:01

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23 FEB 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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09 MAR 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	09 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 APR 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐ 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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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 <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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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 <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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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 <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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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°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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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18 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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13 JUL 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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20 JUL 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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27 JUL 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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>	13 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2022 23:59
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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 754

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

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US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

**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 ☐

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3812062

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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"/>

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

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US3812062

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:53:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 08:38:46

US3812062

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812062

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812062

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:36

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812062

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812062

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:50

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 19:45:34

Generated On: 10 Jun 2021 09:53:42

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

Visit date (dd MMM yyyy)	03 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3812062

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 16:16:36

Generated On: 10 Jun 2021 09:53:42

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 MAR 2021
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 15:20
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812062

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 19:45:34

Generated On: 10 Jun 2021 09:53:42

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 MAR 2021

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

US3812062

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 19:45:34

Generated On: 10 Jun 2021 09:53:42

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 03 MAR 2021

Collection time (00:00-23:59) 15:05 (24 HR)

Collection date and time (derived) 03 MAR 2021 15:05

US3812062

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 19:45:34

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812062

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 00:47:56

Generated On: 10 Jun 2021 09:53:42

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3812062

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 00:47:56

Generated On: 10 Jun 2021 09:53:42

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3812062**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

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*

**US3812062**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812062

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

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 19:45:34

Generated On: 10 Jun 2021 09:53:42

Was this visit performed? Yes ☒  
No ☐

Visit date (dd MMM yyyy) 03 MAR 2021

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

Folder OID UNBLND\_DECIDE

US3812062

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 19:45:34

Generated On: 10 Jun 2021 09:53:42

Date of updated informed consent (dd MMM yyyy) 03 MAR 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 03 MAR 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3812062

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 19:45:34

Generated On: 10 Jun 2021 09:53:42

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 03 MAR 2021

Collection time (00:00-23:59) 15:05 (24 HR)

Collection date and time (derived) 03 MAR 2021 15:05

US3812062

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Mar 2021 19:45:34

Generated On: 10 Jun 2021 09:53:42

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 03 MAR 2021

Collection time (00:00 - 23:59) 15:10

Collection Date and Time (derived) 03 MAR 2021 15:10

US3812062

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 19:35:36

Generated On: 10 Jun 2021 09:53:42

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3812062

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

AEID	USA-US111-2021-MRNA-1273-P30 1000007
Adverse event	WORSENING HYPONATREMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 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)	20 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	20 JAN 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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US3812062

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

Number of Days in ICU	3
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3812062

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

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SUBJECT 3812062 IS A 55-YEAR-OLD FEMALE WHO PRESENTED TO THE ER ON 16 JAN 2021 WITH A CHIEF COMPLAINT OF ALTERED MENTAL STATUS AND FATIGUE AFTER FALLING EARLIER THAT WEEK. SUBJECT HAS MEDICAL HISTORY OF DEPRESSION, ANXIETY, BIPOLAR DISORDER, AND ALCOHOL ABUSE. OTHER PERTINENT HISTORY INCLUDES HTN, CEREBRAL ANEURYSM WITH CLIPPING, HYPOKALEMIA, HYPONATREMIA, AND GRAND MAL SEIZURE. LABS OBTAINED IN THE ER SHOWED A SODIUM LEVEL OF 106 MMOL/L, POTASSIUM OF 2.4 MMOL/L, MAGNESIUM OF 2.0 MG/DL, AN ELEVATED TROPONIN LEVEL OF 17 NG/L, AND ELEVATED LFTS. TSH AND CORTISOL LEVELS WERE NORMAL. LABS ALSO SHOWED A SERUM OSMOLALITY OF 217 MOSM/KG, URINE OSMOLALITY OF 249 MOSM/KG, AND URINE SODIUM OF 47 MMOL/L.

SUBJECT RECEIVED 100 ML IV BOLUS OF 3% SODIUM CHLORIDE, 2 GRAMS OF

US3812062

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

---

MAGNESIUM SULFATE, AND 20  
MEQ OF POTASSIUM CHLORIDE  
WHILE IN THE ER. CHEST  
X-RAY OBTAINED IN THE ER  
WAS UNMARKABLE. EKG  
SHOWED PROLONGED QT  
INTERVAL. CT SCAN OF THE  
HEAD SHOWED CHRONIC  
ISCHEMIC CHANGES, BRAIN  
ATROPHY, AND ANEURYSM  
CLIPPING WITHOUT  
INTRACRANIAL HEMORRHAGE.  
SUBJECT WAS TRANSFERRED  
TO THE ICU FOR THE  
FOLLOWING INPATIENT  
DIAGNOSES: ALTERED  
MENTAL STATUS,  
HYPONATREMIA,  
HYPOKALEMIA, AND  
PROLONGED QT INTERVAL.  
BMP WAS OBTAINED Q4HRS.  
SODIUM CHLORIDE 0.9%  
INFUSION WAS GIVEN  
THROUGHOUT THE STAY BUT  
SPECIFIC DOSAGE AND TIMES  
WERE NOT DOCUMENTED IN  
MEDICAL RECORD. SUBJECT  
WAS DISCHARGED WITH THE  
FOLLOWING MEDICATIONS:  
AMLODIPINE 10 MG DAILY,  
NICOTINE PATCH DAILY,  
SODIUM CHLORIDE 1GRAM  
TID, THIAMINE 100 MG DAILY,  
AND ZYPREXA 20 MG Q HS.

---

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

---

US3812062

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

AEID

Adverse event

HYPOKALEMIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

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)	_____

US3812062

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

AEID	
Adverse event	FALL
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)	14 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)	14 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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 (3)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

AEID	
Adverse event	ELEVATED TROPONIN LEVEL
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 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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 (4)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

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

US3812062

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 21 Apr 2021 14:41:10

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 21 Apr 2021 14:41:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 20 Feb 2021 19:35:36

Generated On: 10 Jun 2021 09:53:42

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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.

---

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication PROZAC

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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 JUL 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)	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 (2)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication ZYPREXA

Prophylaxis Yes ☐  
No ☒

Indication BIPOLAR

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 (2)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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 JUL 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication HYDROXYZINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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 JUL 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 (4)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication ATROVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HIGH CHOLESTEROL

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) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

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 (6)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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 (7)

Data signed: (b) (4) 16 Apr 2021 14:22:41

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Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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 (8)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication ERGOCALCIFEROL

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 50,000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" 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) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication METOPROLOL TARTRATE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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 JUL 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 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 (10)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication LISINOPRIL-10 MG  
HYDROCHLOROTHIAZIDE-12.5  
MG

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 (10)

Data signed: (b) (4) 16 Apr 2021 14:22:41

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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 JUL 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 JAN 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 (11)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication MOTRIN [IBUPROFEN]

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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)		07 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication PPV23 VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PNEUMONIA PREVENTION

Dose per administration 1

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

If dose unit is Other, specify DOSE

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) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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 JUL 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 JUL 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 (13)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication MOTRIN [IBUPROFEN]

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 800

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) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 AUG 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 1

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

If dose unit is Other, specify DOSE

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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)	16 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)		16 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 (15)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN AT INJECTION SITE

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 (15)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 4 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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 (16)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPONATREMIA

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 (16)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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)	20 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) 20 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication VITAMIN B1

Prophylaxis Yes ☐  
No ☒

Indication HYPONATREMIA

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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US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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)	20 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) 20 FEB 2021		
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"/>

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPONATREMIA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPONATREMIA

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

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

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐  
No ☒

Indication HYPONATREMIA

Dose per administration 2/50

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

If dose unit is Other, specify G/ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPOKALEMIA

Dose per administration 20/100

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

If dose unit is Other, specify MEQ/ME

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 (21)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication SODIUM CHLORIDE 3%

Prophylaxis Yes ☐  
No ☒

Indication HYPONATREMIA

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 (22)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 16 JAN 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

Name of Medication NICOTINE 21MG/24 HOUR  
PATCH

Prophylaxis Yes ☐  
No ☒

Indication NICOTINE ADDICTION

Dose per administration 1

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

If dose unit is Other, specify PATCH

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  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 14:22:41

Generated On: 10 Jun 2021 09:53:42

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

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Mar 2021 19:45:34

Generated On: 10 Jun 2021 09:53:42

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Mar 2021 19:45:33

Generated On: 10 Jun 2021 09:53:42

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 JAN 2021	CHEST X-RAY	Adverse Event	
16 JAN 2021	CT HEAD WITHOUT CONTRAST	Adverse Event	
19 JAN 2021	US CAROTID DOPPLER	Adverse Event	
19 JAN 2021	ECHO	Adverse Event	
16 JAN 2021	EKG 12-LEAD	Adverse Event	
17 JAN 2021	EKG 12 LEAD	Adverse Event	

US3812062

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:53:42

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

US3812062

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:53:42

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 ☐

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 00:47:56

Generated On: 10 Jun 2021 09:53:42

SAEID	USA-US111-2021-MRNA-1273-P301000007
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 00:47:56

Generated On: 10 Jun 2021 09:53:42

SAEID	USA-US111-2021-MRNA-1273-P301000007
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	20/JAN/2021 07:41
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

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 00:47:56

Generated On: 10 Jun 2021 09:53:42

SAEID	USA-US111-2021-MRNA-1273-P301000007
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/FEB/2021 11:30
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

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 00:47:56

Generated On: 10 Jun 2021 09:53:42

SAEID	USA-US111-2021-MRNA-1273-P301000007
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/MAR/2021 14:30
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

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 00:47:56

Generated On: 10 Jun 2021 09:53:42

SAEID	USA-US111-2021-MRNA-1273-P301000007
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/MAR/2021 06:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 08 Apr 2021 00:47:56

Generated On: 10 Jun 2021 09:53:42

SAEID	USA-US111-2021-MRNA-1273-P301000007
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/MAR/2021 14:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 08 Apr 2021 00:47:56

Generated On: 10 Jun 2021 09:53:42

SAEID	USA-US111-2021-MRNA-1273-P301000007
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	07/APR/2021 14:23
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

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (7)

Data signed: (b) (4) 08 Apr 2021 00:47:56

Generated On: 10 Jun 2021 09:53:42

SAEID	USA-US111-2021-MRNA-1273-P301000007
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	07/APR/2021 14:48
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

US3812062 (Prod: Sundance Clinical Research - Platinum - PPDS)

**US3812062**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:53:42**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User entered 'US3812062'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 17:24:28

**US3812062**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	06 Aug 2020 17:49:27

**US3812062**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 17:24:29

**US3812062**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	06 Aug 2020 17:49:27

**US3812062**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'SCRN'	System	06 Aug 2020 17:49:27

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

**Date of Birth (MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered (b) (6) 1965'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 17:24:30

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '55'	Heather Cherniawski (b) (4)	06 Aug 2020 17:51:28

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'YEARS'	System	06 Aug 2020 17:51:28

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '55'	System	06 Aug 2020 17:49:42

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Female (F)'	Heather Cherniawski (b) (4)	06 Aug 2020 17:51:28

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Heather Cherniawski (b) (4)	06 Aug 2020 17:51:28

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'I'	Heather Cherniawski (b) (4)	06 Aug 2020 17:51:28

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 17:51:28

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 17:51:28

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 17:51:28

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Heather Cherniawski	06 Aug 2020 17:51:28

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 17:51:28

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Heather Cherniawski (b) (4)	06 Aug 2020 17:51:28

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 17:51:28

**US3812062**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:53:42**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Heather Cherniawski (b) (4)	06 Aug 2020 17:51:28

US3812062

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:53:42

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:15:35
User entered '6 Aug 2020'	(b) (4)	
	Heather Cherniawski	06 Aug 2020 17:49:42
	(b) (4)	

**US3812062**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Aug 2020'	System	06 Aug 2020 17:49:42

**US3812062**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2020'	System	06 Aug 2020 17:49:42

**US3812062**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:42**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Amendment 1 (1)'	Heather Cherniawski	06 Aug 2020 17:49:42

**US3812062**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Heather Cherniawski	06 Aug 2020 17:49:42

**US3812062**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Heather Cherniawski (b) (4)	06 Aug 2020 17:49:42

**US3812062**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:42**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Heather Cherniawski (b) (4)	06 Aug 2020 17:49:42

**US3812062**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:42**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Heather Cherniawski	06 Aug 2020 17:49:42

**US3812062**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:42**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 17:24:29

**US3812062**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:53:42**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'I'	System	06 Aug 2020 17:49:55

**US3812062**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	06 Aug 2020 17:49:55

**US3812062**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:53:42**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:39:15

US3812062

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:53:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:41:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:41:19
Data point term sent to Coder	System	07 Aug 2020 16:40:06
User entered 'POST MENOPAUSAL'	Breanna Galibert (b) (4)	07 Aug 2020 16:39:36

**US3812062**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 2017'	Breanna Galibert (b) (4)	07 Aug 2020 16:39:36

**US3812062**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:39:36

**US3812062**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:39:36

**US3812062**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:39:36

**US3812062**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:39:36

**US3812062**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 2017'	System	07 Aug 2020 16:39:36

**US3812062**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2017'	System	07 Aug 2020 16:39:36

**US3812062**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:39:36

**US3812062**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:39:36

US3812062

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:53:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Psychiatric disorders, HLGHT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:42:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:42:20
Data point term sent to Coder	System	07 Aug 2020 16:41:08
User entered 'BIPOLAR'	Breanna Galibert (b) (4)	07 Aug 2020 16:40:43

**US3812062**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 1998'	Breanna Galibert (b) (4)	07 Aug 2020 16:40:43

**US3812062**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:40:43

**US3812062**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:40:43

**US3812062**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:40:43

**US3812062**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:40:43

**US3812062**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 1998'	System	07 Aug 2020 16:40:43

**US3812062**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1998'	System	07 Aug 2020 16:40:43

**US3812062**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:40:43

**US3812062**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:40:43

US3812062

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:53:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:42:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:42:19
Data point term sent to Coder	System	07 Aug 2020 16:41:09
User entered 'ANXIETY'	Breanna Galibert (b) (4)	07 Aug 2020 16:40:55

US3812062

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 1998'	Breanna Galibert (b) (4)	07 Aug 2020 16:40:55

**US3812062**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:40:55

**US3812062**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:40:55

**US3812062**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:40:55

**US3812062**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:40:55

**US3812062**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 1998'	System	07 Aug 2020 16:40:55

**US3812062**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1998'	System	07 Aug 2020 16:40:55

**US3812062**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:40:55

**US3812062**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:40:55

US3812062

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User closed query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4)	22 Sep 2020 15:59:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\23.0.	Coder Import (b) (4)	18 Sep 2020 21:44:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	18 Sep 2020 21:44:45
Data point term sent to Coder	System	18 Sep 2020 21:43:06
Query 'Per MM, please expand the abbreviation.' answered with 'expanded per query' (Site from DM).	Anya Penly (b) (4)	18 Sep 2020 21:42:37
Coding entries removed.	(b) (4)	
User entered 'Degenerative disc disease' reason for change: Data Entry Error	Anya Penly (b) (4)	18 Sep 2020 21:42:29
User opened query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\23.0.	(b) (4), (b) (6)	15 Sep 2020 09:16:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 05:32:19
Data point term sent to Coder	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\23.0.	System	14 Aug 2020 05:30:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 05:30:17
	(b) (4)	
	Coder Import (b) (4)	14 Aug 2020 05:30:17
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:53:42

[Condition](#)

Audit	User	Time (GMT)
Query 'DM-Coding: Please expand/spell out the reported abbreviation DDD and provide the full text. ' canceled (Site from System).	Coder Import (b) (4)	14 Aug 2020 05:30:09
User opened query 'DM-Coding: Please expand/spell out the reported abbreviation DDD and provide the full text. ' (Site from System).	Coder Import (b) (4)	14 Aug 2020 05:27:09
Data point term sent to Coder	System	07 Aug 2020 16:41:10
User entered 'DDD'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:05
	(b) (4)	

**US3812062**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 2012'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:05

**US3812062**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:05

**US3812062**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:05

**US3812062**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:41:05

**US3812062**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:05

**US3812062**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 2012'	System	07 Aug 2020 16:41:05

**US3812062**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2012'	System	07 Aug 2020 16:41:05

**US3812062**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:41:05

**US3812062**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:41:05

US3812062

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
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: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:43:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:43:21
Data point term sent to Coder	System	07 Aug 2020 16:42:10
User entered 'CHRONIC BACK PAIN'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:17

**US3812062**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 2013'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:17

**US3812062**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:17

**US3812062**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:17

**US3812062**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:41:17

**US3812062**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:17

**US3812062**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 2013'	System	07 Aug 2020 16:41:17

**US3812062**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2013'	System	07 Aug 2020 16:41:17

**US3812062**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:41:17

**US3812062**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:41:17

US3812062

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:53:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:43:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:43:21
Data point term sent to Coder	System	07 Aug 2020 16:42:12
User entered 'HIGH CHOLESTEROL'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:32

**US3812062**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Feb 2020'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:32

**US3812062**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:32

**US3812062**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:32

**US3812062**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:41:32

**US3812062**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:32

**US3812062**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Feb 2020'	System	07 Aug 2020 16:41:32

**US3812062**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2020'	System	07 Aug 2020 16:41:32

**US3812062**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:41:32

**US3812062**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:41:32

US3812062

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:43:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:43:21
Data point term sent to Coder	System	07 Aug 2020 16:42:13
User entered 'VITAMIN D DEFICIENCY'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:52

**US3812062**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 2019'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:52

**US3812062**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:52

**US3812062**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:52

**US3812062**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:41:52

**US3812062**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:41:52

**US3812062**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 2019'	System	07 Aug 2020 16:41:52

**US3812062**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2019'	System	07 Aug 2020 16:41:52

**US3812062**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:41:52

**US3812062**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:41:52

US3812062

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:53:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:43:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:43:21
Data point term sent to Coder	System	07 Aug 2020 16:42:13
User entered 'HYPERTENSION'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:05

**US3812062**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Jul 2017'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:05

**US3812062**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:05

**US3812062**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:05

**US3812062**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:42:05

**US3812062**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:05

**US3812062**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jul 2017'	System	07 Aug 2020 16:42:05

**US3812062**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2017'	System	07 Aug 2020 16:42:05

**US3812062**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:42:05

**US3812062**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:42:05

US3812062

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Benign and malignant breast neoplasms, PT: Fibrocystic breast disease, LLT: Fibrocystic breast - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:40:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:40:09
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Data point term sent to Coder	System	25 Mar 2021 17:39:45
Coding entries removed.	Breanna Galibert (b) (4)	25 Mar 2021 17:39:21
Signature has been broken.	(b) (4) Breanna Galibert (b) (4)	25 Mar 2021 17:39:21
User entered 'BILATERAL FIBROCYSTIC BREAST' reason for change: Data Entry Error	(b) (4) Breanna Galibert (b) (4)	25 Mar 2021 17:39:21
User signature succeeded.	(b) (4) Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Benign and malignant breast neoplasms, PT: Fibrocystic breast disease, LLT: Fibrocystic breast - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 18:15:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 18:15:21
Data point term sent to Coder	System	07 Aug 2020 16:43:14
User entered '(B) FIBROCYSTIC BREAST'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:42:29

**US3812062**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Feb 2019'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:29

**US3812062**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:29

**US3812062**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:29

**US3812062**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:42:29

**US3812062**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:29

**US3812062**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Feb 2019'	System	07 Aug 2020 16:42:29

**US3812062**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2019'	System	07 Aug 2020 16:42:29

**US3812062**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:42:29

**US3812062**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:42:29

US3812062

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:53:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:44:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:44:21
Data point term sent to Coder	System	07 Aug 2020 16:43:15
User entered 'HYPONATREMIA'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:49

**US3812062**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 2012'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:49

**US3812062**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:49

**US3812062**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:49

**US3812062**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:42:49

**US3812062**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:42:49

**US3812062**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 2012'	System	07 Aug 2020 16:42:49

**US3812062**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2012'	System	07 Aug 2020 16:42:49

**US3812062**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:42:49

**US3812062**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:42:49

US3812062

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User closed query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 09:54:27
Query 'Per DM CLR: Please note that there is no Con Anya Penly Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Per Investigator: subject denies having any treatment status post one occurrence of grandmal seizure' (Site from DM).	(b) (4) (b) (4)	28 Oct 2020 21:32:38
User opened query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 04:23:49
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Generalised tonic-clonic seizures, PT: Generalised tonic-clonic seizure, LLT: Grand mal seizure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:19:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 09:19:11
Data point term sent to Coder	System	07 Aug 2020 16:43:16
User entered 'GRANDMAL SEIZURE'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:43:09

**US3812062**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 2012'	Breanna Galibert (b) (4)	07 Aug 2020 16:43:09

**US3812062**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:43:09

**US3812062**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:43:09

**US3812062**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 2012'	Breanna Galibert (b) (4)	07 Aug 2020 16:43:09

**US3812062**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:43:09

**US3812062**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 2012'	System	07 Aug 2020 16:43:09

**US3812062**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2012'	System	07 Aug 2020 16:43:09

**US3812062**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 2012'	System	07 Aug 2020 16:43:09

**US3812062**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2012'	System	07 Aug 2020 16:43:09

US3812062

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:45:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:45:10
Data point term sent to Coder	System	07 Aug 2020 16:44:17
User entered 'HYPOKALEMIA'	Breanna Galibert (b) (4)	07 Aug 2020 16:43:53

**US3812062**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 2012'	Breanna Galibert (b) (4)	07 Aug 2020 16:43:53

**US3812062**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:43:53

US3812062

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:53:42

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
Signature has been broken.	Anya Penly (b) (4)	06 Apr 2021 20:59:59
User entered 'No (N)' reason for change: New Information	Anya Penly (b) (4)	06 Apr 2021 20:59:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:43:53

US3812062

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
Signature has been broken.	Anya Penly (b) (4)	06 Apr 2021 20:59:59
User entered '11 Jul 2019' reason for change: New Information	Anya Penly (b) (4)	06 Apr 2021 20:59:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:43:53

**US3812062**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:43:53

**US3812062**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 2012'	System	07 Aug 2020 16:43:53

**US3812062**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2012'	System	07 Aug 2020 16:43:53

**US3812062**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jul 2019'	System	06 Apr 2021 20:59:59
User entered empty.	System	07 Aug 2020 16:43:53

**US3812062**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2019'	System	06 Apr 2021 20:59:59
User entered empty.	System	07 Aug 2020 16:43:53

US3812062

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Elbow bursitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:22:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:22:13
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Data point term sent to Coder	System	25 Mar 2021 17:40:46
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	25 Mar 2021 17:39:53
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	25 Mar 2021 17:39:53
User entered 'RIGHT ELBOW BURSITIS' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	25 Mar 2021 17:39:53
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Elbow bursitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 20:11:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 20:11:30
Data point term sent to Coder	System	07 Aug 2020 16:44:18
User entered '(R) ELBOW BURSITIS'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:44:14

**US3812062**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '01 May 2020'	Breanna Galibert (b) (4)	07 Aug 2020 16:44:14

**US3812062**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:44:14

**US3812062**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:44:14

**US3812062**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:44:14

**US3812062**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:44:14

**US3812062**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'May 2020'	System	07 Aug 2020 16:44:14

**US3812062**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2020'	System	07 Aug 2020 16:44:14

**US3812062**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:44:14

**US3812062**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:44:14

US3812062

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of arm - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:56:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:56:29
Data point term sent to Coder	System	25 Mar 2021 17:40:46
Coding entries removed.	Breanna Galibert (b) (4)	25 Mar 2021 17:40:02
Signature has been broken.	Breanna Galibert (b) (4)	25 Mar 2021 17:40:02
User entered 'RIGHT ELBOW CELLULITIS' reason for change: Data Entry Error	Breanna Galibert (b) (4)	25 Mar 2021 17:40:02
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of arm - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 20:12:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 20:12:16
Data point term sent to Coder	System	07 Aug 2020 16:45:20
User entered '(R) ELBOW CELLULITIS'	Breanna Galibert (b) (4)	07 Aug 2020 16:44:38

**US3812062**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '01 May 2020'	Breanna Galibert (b) (4)	07 Aug 2020 16:44:38

**US3812062**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:44:38

**US3812062**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:44:38

**US3812062**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '01 Jun 2020'	Breanna Galibert (b) (4)	07 Aug 2020 16:44:38

**US3812062**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:44:38

**US3812062**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'May 2020'	System	07 Aug 2020 16:44:38

**US3812062**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2020'	System	07 Aug 2020 16:44:38

**US3812062**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jun 2020'	System	07 Aug 2020 16:44:38

**US3812062**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2020'	System	07 Aug 2020 16:44:38

US3812062

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermal and epidermal conditions NEC, PT: Skin discolouration, LLT: Discoloration skin - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:58:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:58:10
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:45:35
Data point term sent to Coder	System	25 Mar 2021 17:40:46
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	25 Mar 2021 17:40:13
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	25 Mar 2021 17:40:13
User entered 'BILATERAL UPPER EXTREMITY DISCOLORATION' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	25 Mar 2021 17:40:13
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermal and epidermal conditions NEC, PT: Skin discolouration, LLT: Skin discolouration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 20:11:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 20:11:30
Data point term sent to Coder	System	07 Aug 2020 16:46:22
User entered '(B) UPPER EXTREMITY DISCOLORATION'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:45:59

**US3812062**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN May 2015'	Breanna Galibert (b) (4)	07 Aug 2020 16:45:59

**US3812062**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:45:59

**US3812062**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:45:59

**US3812062**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:45:59

**US3812062**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:45:59

**US3812062**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'May 2015'	System	07 Aug 2020 16:45:59

**US3812062**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2015'	System	07 Aug 2020 16:45:59

**US3812062**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:45:59

**US3812062**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:45:59

US3812062

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual impairment, LLT: Visual impairment - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:56:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	25 Mar 2021 17:56:29
Data point term sent to Coder	System	25 Mar 2021 17:40:47
Coding entries removed.	Breanna Galibert (b) (4)	25 Mar 2021 17:40:22
Signature has been broken.	(b) (4)	25 Mar 2021 17:40:22
User entered 'BILATERAL VISION IMPAIRMENT' reason for change: Data Entry Error	Breanna Galibert (b) (4)	25 Mar 2021 17:40:22
User signature succeeded.	(b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual impairment, LLT: Visual impairment - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:47:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	07 Aug 2020 16:47:12
Data point term sent to Coder	System	07 Aug 2020 16:46:23
User entered '(B) VISION IMPAIRMENT'	Breanna Galibert (b) (4)	07 Aug 2020 16:46:19
	(b) (4)	

**US3812062**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 1975'	Breanna Galibert (b) (4)	07 Aug 2020 16:46:19

**US3812062**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:46:19

**US3812062**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:46:19

**US3812062**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:46:19

**US3812062**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:46:19

**US3812062**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 1975'	System	07 Aug 2020 16:46:19

**US3812062**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1975'	System	07 Aug 2020 16:46:19

**US3812062**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:46:19

**US3812062**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:46:19

US3812062

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User closed query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 16:00:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Hand osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:44:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:44:45
Data point term sent to Coder	System	18 Sep 2020 21:44:06
Query 'Per MM, please expand the abbreviation.' answered with 'expanded per query' (Site from DM).	Anya Penly (b) (4) (b) (4)	18 Sep 2020 21:43:17
Coding entries removed.	Anya Penly (b) (4) (b) (4)	18 Sep 2020 21:43:08
User entered 'bilateral hand osteoarthritis' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	18 Sep 2020 21:43:08
User opened query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 22:10:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Hand osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 20:10:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 20:10:20
Data point term sent to Coder	System	07 Aug 2020 16:47:25
User entered '(B) HAND OA'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:46:42

**US3812062**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 2018'	Breanna Galibert (b) (4)	07 Aug 2020 16:46:42

**US3812062**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:46:42

**US3812062**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:46:42

**US3812062**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:46:42

**US3812062**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:46:42

**US3812062**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 2018'	System	07 Aug 2020 16:46:42

**US3812062**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2018'	System	07 Aug 2020 16:46:42

**US3812062**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:46:42

**US3812062**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:46:42

US3812062

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:53:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system aneurysms and dissections, PT: Intracranial aneurysm, LLT: Aneurysm cerebral - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:48:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:48:17
Data point term sent to Coder	System	07 Aug 2020 16:47:26
User entered 'BRAIN ANEURYSM'	Breanna Galibert (b) (4)	07 Aug 2020 16:47:01

**US3812062**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Nov 1998'	Breanna Galibert (b) (4)	07 Aug 2020 16:47:01

**US3812062**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:47:01

**US3812062**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:47:01

**US3812062**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Nov 1998'	Breanna Galibert (b) (4)	07 Aug 2020 16:47:01

**US3812062**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:47:01

**US3812062**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Nov 1998'	System	07 Aug 2020 16:47:01

**US3812062**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1998'	System	07 Aug 2020 16:47:01

**US3812062**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Nov 1998'	System	07 Aug 2020 16:47:01

**US3812062**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1998'	System	07 Aug 2020 16:47:01

US3812062

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Skull and brain therapeutic procedures, PT: Craniotomy, LLT: Craniotomy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:49:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 16:49:20
Data point term sent to Coder	System	07 Aug 2020 16:48:29
User entered 'CRANIOTOMY'	Breanna Galibert (b) (4)	07 Aug 2020 16:47:46

**US3812062**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Nov 1998'	Breanna Galibert (b) (4)	07 Aug 2020 16:47:46

**US3812062**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:47:46

**US3812062**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:47:46

**US3812062**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Nov 1998'	Breanna Galibert (b) (4)	07 Aug 2020 16:47:46

**US3812062**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:47:46

**US3812062**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Nov 1998'	System	07 Aug 2020 16:47:46

**US3812062**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1998'	System	07 Aug 2020 16:47:46

**US3812062**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Nov 1998'	System	07 Aug 2020 16:47:46

**US3812062**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1998'	System	07 Aug 2020 16:47:46

US3812062

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Intra-cerebral aneurysm operation, LLT: Intra-cerebral aneurysm clipping - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 21:47:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 21:47:20
Data point term sent to Coder	System	06 Apr 2021 21:05:08
Coding entries removed.	Anya Penly (b) (4)	06 Apr 2021 21:04:31
Signature has been broken.	(b) (4)	
	Anya Penly (b) (4)	06 Apr 2021 21:04:31
User entered 'BRAIN ANEURYSM CLIPPING'	(b) (4)	
reason for change: Data Entry Error	Anya Penly (b) (4)	06 Apr 2021 21:04:31
User signature succeeded.	(b) (4)	
	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system aneurysms and dissections, PT: Intracranial aneurysm, LLT: Aneurysm cerebral - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 23:32:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Aug 2020 23:32:22
Data point term sent to Coder	System	07 Aug 2020 16:48:29
User entered 'BRAIN ANEURYSM DIPPING'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:05
	(b) (4)	

**US3812062**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Nov 1998'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Nov 1998'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Nov 1998'	System	07 Aug 2020 16:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1998'	System	07 Aug 2020 16:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Nov 1998'	System	07 Aug 2020 16:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1998'	System	07 Aug 2020 16:48:05

US3812062

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:53:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User closed query 'Per DM CLR: Please specify the location and/or type of STEEL PLATE PLACEMENT (e.g. Open Reduction and Internal Fixation of Right Tibia, Spinal Fusion etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 09:51:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Medical device implantation, LLT: Insertion of surgical hardware - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 10:21:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 10:21:44
Data point term sent to Coder	System	28 Oct 2020 21:34:13
Query 'Per DM CLR: Please specify the location and/or type of STEEL PLATE PLACEMENT (e.g. Open Reduction and Internal Fixation of Right Tibia, Spinal Fusion etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Per Investigator: skull steel plate placement due to past medical history of craniotomy in 1998' (Site from DM).	Anya Penly (b) (4) (b) (4)	28 Oct 2020 21:33:51
Coding entries removed.	Anya Penly (b) (4) (b) (4)	28 Oct 2020 21:33:17
User entered 'skull STEEL PLATE PLACEMENT' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	28 Oct 2020 21:33:17

US3812062

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the location and/or type of STEEL PLATE PLACEMENT (e.g. Open Reduction and Internal Fixation of Right Tibia, Spinal Fusion etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 04:24:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Medical device implantation, LLT: Insertion of surgical hardware - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 11:16:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 11:16:42
Data point term sent to Coder	System	07 Aug 2020 16:48:29
User entered 'STEEL PLATE PLACEMENT'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:48:23

**US3812062**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Nov 1998'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:23

**US3812062**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:23

**US3812062**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:23

**US3812062**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Nov 1998'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:23

**US3812062**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:23

**US3812062**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Nov 1998'	System	07 Aug 2020 16:48:23

**US3812062**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1998'	System	07 Aug 2020 16:48:23

**US3812062**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Nov 1998'	System	07 Aug 2020 16:48:23

**US3812062**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1998'	System	07 Aug 2020 16:48:23

US3812062

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:53:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Social circumstances, HLT: Lifestyle issues, HLT: Social issues NEC, PT: Substance use, LLT: Marijuana use - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 10:07:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Sep 2020 10:07:47
Data point term sent to Coder	System	07 Aug 2020 16:49:30
User entered 'OCCASIONAL MARIJUANA USE'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:42

**US3812062**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 1975'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:42

**US3812062**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:42

**US3812062**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:42

**US3812062**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:48:42

**US3812062**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:48:42

**US3812062**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 1975'	System	07 Aug 2020 16:48:42

**US3812062**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1975'	System	07 Aug 2020 16:48:42

**US3812062**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:48:42

**US3812062**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	07 Aug 2020 16:48:42

US3812062

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:53:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:49:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:49:06
Data point term sent to Coder	System	13 Aug 2020 20:47:30
User entered 'OSTEOPENIA'	Breanna Galibert (b) (4)	13 Aug 2020 20:46:55

**US3812062**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 2019'	Breanna Galibert (b) (4)	13 Aug 2020 20:46:55

**US3812062**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	13 Aug 2020 20:46:55

**US3812062**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Aug 2020 20:46:55

**US3812062**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	13 Aug 2020 20:46:55

**US3812062**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	13 Aug 2020 20:46:55

**US3812062**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 2019'	System	13 Aug 2020 20:46:55

**US3812062**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2019'	System	13 Aug 2020 20:46:55

**US3812062**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	13 Aug 2020 20:46:55

**US3812062**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	13 Aug 2020 20:46:55

US3812062

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
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: Localized rash - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 02:04:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 02:04:11
Data point term sent to Coder	System	13 Aug 2020 20:47:32
User entered 'ABDOMINAL RASH'	Breanna Galibert (b) (4)	13 Aug 2020 20:47:26

**US3812062**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Jul 2020'	Breanna Galibert (b) (4)	13 Aug 2020 20:47:26

**US3812062**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	13 Aug 2020 20:47:26

**US3812062**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	13 Aug 2020 20:47:26

**US3812062**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Jul 2020'	Breanna Galibert (b) (4)	13 Aug 2020 20:47:26

**US3812062**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	13 Aug 2020 20:47:26

**US3812062**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jul 2020'	System	13 Aug 2020 20:47:26

**US3812062**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2020'	System	13 Aug 2020 20:47:26

**US3812062**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jul 2020'	System	13 Aug 2020 20:47:26

**US3812062**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2020'	System	13 Aug 2020 20:47:26

US3812062

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of arm - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:57:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:57:34
Data point term sent to Coder	System	25 Mar 2021 17:41:48
Coding entries removed.	Breanna Galibert (b) (4)	25 Mar 2021 17:41:22
Signature has been broken.	Breanna Galibert (b) (4)	25 Mar 2021 17:41:22
User entered 'RIGHT ELBOW CELLULITIS' reason for change: Data Entry Error	Breanna Galibert (b) (4)	25 Mar 2021 17:41:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of arm - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:49:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:49:12
Data point term sent to Coder	System	13 Aug 2020 20:48:33
User entered '(R) ELBOW CELLULITIS'	Breanna Galibert (b) (4)	13 Aug 2020 20:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '24 Jun 2020'	Breanna Galibert (b) (4)	13 Aug 2020 20:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	13 Aug 2020 20:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	13 Aug 2020 20:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN Jul 2020'	Breanna Galibert (b) (4)	13 Aug 2020 20:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	13 Aug 2020 20:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jun 2020'	System	13 Aug 2020 20:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2020'	System	13 Aug 2020 20:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jul 2020'	System	13 Aug 2020 20:48:05

**US3812062**

**Folder: Screening**

**Form: Medical History (25)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2020'	System	13 Aug 2020 20:48:05

US3812062

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:53:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:49:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 20:49:09
Data point term sent to Coder	System	13 Aug 2020 20:48:34
User entered 'OSTEOPOROSIS'	Breanna Galibert (b) (4)	13 Aug 2020 20:48:24

**US3812062**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 2019'	Breanna Galibert (b) (4)	13 Aug 2020 20:48:24

**US3812062**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	13 Aug 2020 20:48:24

**US3812062**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Aug 2020 20:48:24

**US3812062**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	13 Aug 2020 20:48:24

**US3812062**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	13 Aug 2020 20:48:24

**US3812062**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 2019'	System	13 Aug 2020 20:48:24

**US3812062**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '2019'	System	13 Aug 2020 20:48:24

**US3812062**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	13 Aug 2020 20:48:24

**US3812062**

**Folder: Screening**

**Form: Medical History (26)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	13 Aug 2020 20:48:24

US3812062

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol abuse, LLT: Alcohol abuse - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:43:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:43:30
Data point term sent to Coder	System	25 Mar 2021 17:42:49
User entered 'ALCOHOL ABUSE'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:11

**US3812062**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'UN UNK 1986'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:11

**US3812062**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '0'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:11

**US3812062**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'No (N)'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:11

**US3812062**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'UN UNK 1988'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:11

**US3812062**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '0'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:11

**US3812062**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 1986'	System	25 Mar 2021 17:42:11

**US3812062**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1986'	System	25 Mar 2021 17:42:11

**US3812062**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 1988'	System	25 Mar 2021 17:42:11

**US3812062**

**Folder: Screening**

**Form: Medical History (29)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1988'	System	25 Mar 2021 17:42:11

US3812062

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Caesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:43:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:43:29
Data point term sent to Coder	System	25 Mar 2021 17:42:49
User entered 'Caesarean section'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:35

**US3812062**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '21 Mar 1989'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:35

**US3812062**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '0'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:35

**US3812062**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'No (N)'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:35

**US3812062**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '21 Mar 1989'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:35

**US3812062**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '0'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:35

**US3812062**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Mar 1989'	System	25 Mar 2021 17:42:35

**US3812062**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1989'	System	25 Mar 2021 17:42:35

**US3812062**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Mar 1989'	System	25 Mar 2021 17:42:35

**US3812062**

**Folder: Screening**

**Form: Medical History (30)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1989'	System	25 Mar 2021 17:42:35

US3812062

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:43:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:43:29
Data point term sent to Coder	System	25 Mar 2021 17:42:50
User entered 'HEADACHES'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:45

**US3812062**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'UN UNK 1972'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:45

**US3812062**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '0'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:45

**US3812062**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:45

**US3812062**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered empty.	Breanna Galibert (b) (4)	25 Mar 2021 17:42:45

**US3812062**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '0'	Breanna Galibert (b) (4)	25 Mar 2021 17:42:45

**US3812062**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 1972'	System	25 Mar 2021 17:42:45

**US3812062**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1972'	System	25 Mar 2021 17:42:45

**US3812062**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	25 Mar 2021 17:42:45

**US3812062**

**Folder: Screening**

**Form: Medical History (31)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	25 Mar 2021 17:42:45

US3812062

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:44:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:44:29
Data point term sent to Coder	System	25 Mar 2021 17:43:51
User entered 'MIGRAINES'	Breanna Galibert (b) (4)	25 Mar 2021 17:43:00

**US3812062**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'UN UNK 1998'	Breanna Galibert (b) (4)	25 Mar 2021 17:43:00

**US3812062**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '0'	Breanna Galibert (b) (4)	25 Mar 2021 17:43:00

**US3812062**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	25 Mar 2021 17:43:00

**US3812062**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered empty.	Breanna Galibert (b) (4)	25 Mar 2021 17:43:00

**US3812062**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '0'	Breanna Galibert (b) (4)	25 Mar 2021 17:43:00

**US3812062**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 1998'	System	25 Mar 2021 17:43:00

**US3812062**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1998'	System	25 Mar 2021 17:43:00

**US3812062**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	25 Mar 2021 17:43:00

**US3812062**

**Folder: Screening**

**Form: Medical History (32)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	25 Mar 2021 17:43:00

US3812062

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 09:53:42

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 14:22:42
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Nicotine dependence, LLT: Nicotine addiction - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:24:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:24:54
Data point term sent to Coder	System	15 Apr 2021 19:24:39
Coding entries removed.	Angie Kean (b) (4)	15 Apr 2021 19:23:48
Signature has been broken.	(b) (4)	
	Angie Kean (b) (4)	15 Apr 2021 19:23:48
User entered 'nicotine addiction' reason for change:	(b) (4)	
New Information	Angie Kean (b) (4)	15 Apr 2021 19:23:48
User signature succeeded.	(b) (4)	
	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Smoker - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 17:44:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	25 Mar 2021 17:44:29
User entered 'SMOKER'	System	25 Mar 2021 17:43:51
	Breanna Galibert (b) (4)	25 Mar 2021 17:43:07
	(b) (4)	

**US3812062**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'UN UNK 1983'	Breanna Galibert (b) (4)	25 Mar 2021 17:43:07

**US3812062**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '0'	Breanna Galibert (b) (4)	25 Mar 2021 17:43:07

**US3812062**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	25 Mar 2021 17:43:07

**US3812062**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered empty.	Breanna Galibert (b) (4)	25 Mar 2021 17:43:07

**US3812062**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '0'	Breanna Galibert (b) (4)	25 Mar 2021 17:43:07

**US3812062**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 1983'	System	25 Mar 2021 17:43:07

**US3812062**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1983'	System	25 Mar 2021 17:43:07

**US3812062**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	25 Mar 2021 17:43:07

**US3812062**

**Folder: Screening**

**Form: Medical History (33)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	25 Mar 2021 17:43:07

US3812062

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:53:42

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:00
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:39:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:39:06
Data point term sent to Coder	System	14 Apr 2021 20:38:30
User entered 'Depression'	Lyly Dang (b) (4)	14 Apr 2021 20:37:47

**US3812062**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:00
User entered 'un UNK 1998'	Lyly Dang (b) (4)	14 Apr 2021 20:37:47

**US3812062**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:00
User entered '0'	Lyly Dang (b) (4)	14 Apr 2021 20:37:47

**US3812062**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:53:42**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:00
User entered 'Yes (Y)'	Lyly Dang (b) (4)	14 Apr 2021 20:37:47

**US3812062**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:00
User entered empty.	Lyly Dang (b) (4)	14 Apr 2021 20:37:47

**US3812062**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:53:42**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:00
User entered '0'	Lyly Dang (b) (4)	14 Apr 2021 20:37:47

**US3812062**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'Jan 1998'	System	14 Apr 2021 20:37:47

**US3812062**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '1998'	System	14 Apr 2021 20:37:47

**US3812062**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	14 Apr 2021 20:37:47

**US3812062**

**Folder: Screening**

**Form: Medical History (34)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered empty.	System	14 Apr 2021 20:37:47

**US3812062**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:50:00

US3812062

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:15:41
User entered '6 Aug 2020'	(b) (4)	
	Breanna Galibert (b) (4)	07 Aug 2020 16:50:00
	(b) (4)	

**US3812062**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '10:57'	Breanna Galibert (b) (4)	07 Aug 2020 16:50:00

**US3812062**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '06 Aug 2020 10:57'	System	11 Nov 2020 16:15:41
User entered '6 Aug 2020 10:57'	System	07 Aug 2020 16:50:00

**US3812062**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '67.4' in	Breanna Galibert (b) (4)	07 Aug 2020 16:50:00
DataPoint set to visible.	System	06 Aug 2020 17:49:55

US3812062

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '153.6' lb	Breanna Galibert (b) (4)	07 Aug 2020 16:50:00
DataPoint set to visible.	System	06 Aug 2020 17:49:55

**US3812062**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
Amendment Manager: User entered '23.82217'	System	16 Sep 2020 23:45:50
User entered '23.8'	System	07 Aug 2020 16:50:00
DataPoint set to visible.	System	06 Aug 2020 17:49:55

**US3812062**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'kg/m2'	System	07 Aug 2020 16:50:00
DataPoint set to visible.	System	06 Aug 2020 17:49:55

US3812062

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	07 Aug 2020 16:50:00

US3812062

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Other (Other)'	Breanna Galibert (b) (4)	07 Aug 2020 16:50:00

US3812062

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	07 Aug 2020 16:50:00

**US3812062**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	07 Aug 2020 16:50:00

**US3812062**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'bpm'	System	07 Aug 2020 16:50:00

US3812062

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	07 Aug 2020 16:50:00

**US3812062**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'breaths/min'	System	07 Aug 2020 16:50:00

US3812062

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	07 Aug 2020 16:50:00

**US3812062**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'mmHg'	System	07 Aug 2020 16:50:00

US3812062

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	07 Aug 2020 16:50:00

**US3812062**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'mmHg'	System	07 Aug 2020 16:50:00

US3812062

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 09:01:07

US3812062

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 09:01:07

**US3812062**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:53:42**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:50:09

US3812062

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.'	Maureen Dempsey (b) (4)	11 Nov 2020 16:15:46
canceled (Site from System).	(b) (4)	
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 10:59:13
User entered '6 Aug 2020'		
	Breanna Galibert (b) (4)	07 Aug 2020 16:50:09
	(b) (4)	

US3812062

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:53:42

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '06 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	11 Nov 2020 16:15:51
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 18:50:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Aug 2020 18:50:47
User entered '6 Aug 2020' reason for change: Data Entry Error	Any Penly (b) (4)	07 Aug 2020 18:50:47
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Aug 2020 16:50:42
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:50:42

US3812062

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:53:42

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:50:42

**US3812062**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:53:42**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Breanna Galibert (b) (4)	07 Aug 2020 16:50:42

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:53:42

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:50:42

US3812062

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:50:42

**US3812062**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:53:42**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:50:42

US3812062

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'UN UNK 2017'	Breanna Galibert (b) (4)	07 Aug 2020 16:50:42

**US3812062**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:53:42**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:50:42

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

**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)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

**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)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

[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)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

**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)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

**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)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

[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)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

**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)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

**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)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'I'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

**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)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

[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)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

**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)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

**US3812062**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:53:42**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

US3812062

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:53:42

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:51:05

**US3812062**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	06 Aug 2020 17:50:07

US3812062

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:16:01
User entered '6 Aug 2020'	(b) (4)	
	Heather Cherniawski	06 Aug 2020 17:50:07
	(b) (4)	

US3812062

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Clinic (Clinic)'	Heather Cherniawski	06 Aug 2020 17:50:07

**US3812062**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'VISIT1'	System	06 Aug 2020 17:50:07

US3812062

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 17:24:31

US3812062

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:42

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 02:35:40
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:35:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 17:24:31
User entered '101560' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 17:24:31

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:42

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 17:24:31

US3812062

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:42

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)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:25

US3812062

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:42

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)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:25

US3812062

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:42

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:25

US3812062

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:42

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:25

US3812062

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:53:42

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:51:25

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:16:07
User entered '6 Aug 2020'	(b) (4)	
	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '10:57'	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

**US3812062**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered '06 Aug 2020 10:57'	System	11 Nov 2020 16:16:07
User entered '6 Aug 2020 10:57'	System	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '98.1' F	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '58'	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'bpm'	System	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '14'	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'breaths/min'	System	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '144'	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'mmHg'	System	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '92'	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'mmHg'	System	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:42

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:53:42

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:16:07
User entered '6 Aug 2020'	(b) (4)	
	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56
	(b) (4)	

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User closed 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).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:40:41
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'DM error' (Site from System).	Anya Penly (b) (4) (b) (4)	08 Aug 2020 14:17:56
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).		07 Aug 2020 16:52:56
User entered '13:10'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered '06 Aug 2020 13:10'	System	11 Nov 2020 16:16:07
User entered '6 Aug 2020 13:10'	System	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '98.0' F	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '52'	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

**US3812062**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'bpm'	System	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '14'	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'breaths/min'	System	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '140'	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'mmHg'	System	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '88'	Breanna Galibert (b) (4)	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'mmHg'	System	07 Aug 2020 16:52:56

US3812062

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:53:12

US3812062

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:42

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:53:12

US3812062

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Heather Cherniawski	06 Aug 2020 17:51:09

US3812062

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Heather Cherniawski	06 Aug 2020 17:51:09

US3812062

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

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 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Heather Cherniawski (b) (4)	06 Aug 2020 17:51:09

US3812062

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 17:51:09

US3812062

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:16:15
User entered '6 Aug 2020'	(b) (4)	
	Heather Cherniawski	06 Aug 2020 17:51:09
	(b) (4)	

US3812062

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '12:38'	Heather Cherniawski	06 Aug 2020 17:51:09

US3812062

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered '06 Aug 2020 12:38'	System	11 Nov 2020 16:16:15
User entered '6 Aug 2020 12:38'	System	06 Aug 2020 17:51:09

US3812062

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski	06 Aug 2020 17:51:09

US3812062

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'ONCE'	System	06 Aug 2020 17:51:09

US3812062

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 17:51:09

US3812062

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:53:27

US3812062

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '06 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	11 Nov 2020 16:16:20
User entered '6 Aug 2020'	Breanna Galibert (b) (4)	07 Aug 2020 16:53:27

**US3812062**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:42**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '12:32'	Breanna Galibert (b) (4)	07 Aug 2020 16:53:27

**US3812062**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered '06 Aug 2020 12:32'	System	11 Nov 2020 16:16:20
User entered '6 Aug 2020 12:32'	System	07 Aug 2020 16:53:27

US3812062

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:53:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '06 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:16:26
User entered '6 Aug 2020'	(b) (4)	
	Breanna Galibert (b) (4)	07 Aug 2020 16:53:38
	(b) (4)	

US3812062

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:53:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:53:38

US3812062

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:53:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:53:38

**US3812062**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:53:42**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '12:35'	Breanna Galibert (b) (4)	07 Aug 2020 16:53:38

**US3812062**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered '06 Aug 2020 12:35'	System	11 Nov 2020 16:16:26
User entered '6 Aug 2020 12:35'	System	07 Aug 2020 16:53:38

US3812062

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:53:42

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:53:38

US3812062

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:53:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:53:38

**US3812062**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:53:42**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:53:38

**US3812062**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered empty.	System	07 Aug 2020 16:53:38

US3812062

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:53:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Aug 2020 20:44:10

**US3812062**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'I'	System	13 Aug 2020 20:44:10

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:22:48', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'dc86e39a-a35d-4e67-af06-11232862673d' User entered 'Yes (Y)'	System	06 Aug 2020 18:23:50
	System	06 Aug 2020 18:23:50

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:23:10', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'dc86e39a-a35d-4e67-af06-11232862673d' User entered '98.0'	System	06 Aug 2020 18:23:50
	System	06 Aug 2020 18:23:50

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:23:23', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'dc86e39a-a35d-4e67-af06-11232862673d' User entered 'Yes (Y)'	System	06 Aug 2020 18:23:50
	System	06 Aug 2020 18:23:50

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed conmed with subject and recorded' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 13:24:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:23:36', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'dc86e39a-a35d-4e67-af06-11232862673d' User entered '1'	Anya Penly (b) (4)	25 Aug 2020 15:43:16
	System	06 Aug 2020 18:23:50
	System	06 Aug 2020 18:23:50
	System	06 Aug 2020 18:23:50

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:23:36', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'dc86e39a-a35d-4e67-af06-11232862673d' User entered '0'	System	06 Aug 2020 18:23:50
	System	06 Aug 2020 18:23:50

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:23:48', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'dc86e39a-a35d-4e67-af06-11232862673d' User entered '06 Aug 2020 13:23'	System	06 Aug 2020 18:23:50
	System	06 Aug 2020 18:23:50

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '06 Aug 2020 12:58'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '06 Aug 2020 15:28'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:03:49', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '46eb2f7a-9650-457b-b86f-30ed0a333180' User entered 'Yes (Y)'	System	07 Aug 2020 14:04:31
	System	07 Aug 2020 14:04:31

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:04:03', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '46eb2f7a-9650-457b-b86f-30ed0a333180' User entered '98.0'	System	07 Aug 2020 14:04:31
	System	07 Aug 2020 14:04:31

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:04:11', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '46eb2f7a-9650-457b-b86f-30ed0a333180' User entered 'No (N)'	System	07 Aug 2020 14:04:31
	System	07 Aug 2020 14:04:31

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:04:28', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '46eb2f7a-9650-457b-b86f-30ed0a333180' User entered '07 Aug 2020 09:04'	System	07 Aug 2020 14:04:31
	System	07 Aug 2020 14:04:31

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '06 Aug 2020 16:23'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 2'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:03:25', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'f1da78e6-6b8c-4821-af71-4180b8965932'	System	08 Aug 2020 00:04:34
User entered 'Yes (Y)'	System	08 Aug 2020 00:04:34

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:03:37', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'f1da78e6-6b8c-4821-af71-4180b8965932' User entered '96.9'	System	08 Aug 2020 00:04:34
	System	08 Aug 2020 00:04:34

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:03:45', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'f1da78e6-6b8c-4821-af71-4180b8965932'	System	08 Aug 2020 00:04:34
User entered 'Yes (Y)'	System	08 Aug 2020 00:04:34

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed conmed with subject and recorded' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 13:24:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:04:08', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'f1da78e6-6b8c-4821-af71-4180b8965932' User entered '1'	Anya Penly (b) (4)	25 Aug 2020 15:43:29
	System	08 Aug 2020 00:04:34
	System	08 Aug 2020 00:04:34
	System	08 Aug 2020 00:04:34

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:04:08', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'f1da78e6-6b8c-4821-af71-4180b8965932' User entered '0'	System	08 Aug 2020 00:04:34
	System	08 Aug 2020 00:04:34

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:04:24', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'f1da78e6-6b8c-4821-af71-4180b8965932' User entered '07 Aug 2020 19:04'	System	08 Aug 2020 00:04:34
	System	08 Aug 2020 00:04:34

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 3'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:57:39', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '95c4a7e9-e4f6-4b30-9ec4-71a094d3f088'	System	09 Aug 2020 01:58:18
User entered 'Yes (Y)'	System	09 Aug 2020 01:58:18

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:57:59', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '95c4a7e9-e4f6-4b30-9ec4-71a094d3f088' User entered '98.0'	System	09 Aug 2020 01:58:18
	System	09 Aug 2020 01:58:18

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:58:06', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '95c4a7e9-e4f6-4b30-9ec4-71a094d3f088'	System	09 Aug 2020 01:58:18
User entered 'No (N)'	System	09 Aug 2020 01:58:18

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:58:15', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '95c4a7e9-e4f6-4b30-9ec4-71a094d3f088' User entered '08 Aug 2020 20:58'	System	09 Aug 2020 01:58:18
	System	09 Aug 2020 01:58:18

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 4'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:17:58', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '8e8eea19-d16b-4185-aca0-5341b4236516' User entered 'Yes (Y)'	System	10 Aug 2020 01:18:28
	System	10 Aug 2020 01:18:28

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:18:14', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '8e8eea19-d16b-4185-aca0-5341b4236516' User entered '96.5'	System	10 Aug 2020 01:18:28
	System	10 Aug 2020 01:18:28

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:18:21', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '8e8eea19-d16b-4185-aca0-5341b4236516' User entered 'No (N)'	System	10 Aug 2020 01:18:28
	System	10 Aug 2020 01:18:28

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:18:26', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '8e8eea19-d16b-4185-aca0-5341b4236516' User entered '09 Aug 2020 20:18'	System	10 Aug 2020 01:18:28
	System	10 Aug 2020 01:18:28

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 5'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:02:36', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '47efcd12-6580-4b9a-8d75-065080388f14' User entered 'Yes (Y)'	System	11 Aug 2020 00:06:18
	System	11 Aug 2020 00:06:18

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:05:51', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '47efcd12-6580-4b9a-8d75-065080388f14' User entered '97.6'	System	11 Aug 2020 00:06:18
	System	11 Aug 2020 00:06:18

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:05:57', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '47efcd12-6580-4b9a-8d75-065080388f14'	System	11 Aug 2020 00:06:18
User entered 'No (N)'	System	11 Aug 2020 00:06:18

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:06:07', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '47efcd12-6580-4b9a-8d75-065080388f14' User entered '10 Aug 2020 19:06'	System	11 Aug 2020 00:06:18
	System	11 Aug 2020 00:06:18

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 6'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:07:41', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'b5ca051d-531a-4c6d-b4c8-5baeb7e5a508' User entered 'Yes (Y)'	System	12 Aug 2020 00:08:11
	System	12 Aug 2020 00:08:11

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:07:51', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'b5ca051d-531a-4c6d-b4c8-5baeb7e5a508' User entered '97.1'	System	12 Aug 2020 00:08:11
	System	12 Aug 2020 00:08:11

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:07:57', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'b5ca051d-531a-4c6d-b4c8-5baeb7e5a508'	System	12 Aug 2020 00:08:11
User entered 'No (N)'	System	12 Aug 2020 00:08:11

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:08:07', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'b5ca051d-531a-4c6d-b4c8-5baeb7e5a508'	System	12 Aug 2020 00:08:11
User entered '11 Aug 2020 19:08'	System	12 Aug 2020 00:08:11

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 7'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:34:28', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2cf7f16a-d817-44cf-982b-eedc631ceac6' User entered 'Yes (Y)'	System	13 Aug 2020 01:35:03
	System	13 Aug 2020 01:35:03

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:34:37', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2cf7f16a-d817-44cf-982b-eedc631ceac6' User entered '97.1'	System	13 Aug 2020 01:35:03
	System	13 Aug 2020 01:35:03

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:34:43', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2cf7f16a-d817-44cf-982b-eedc631ceac6'	System	13 Aug 2020 01:35:03
User entered 'No (N)'	System	13 Aug 2020 01:35:03

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:34:59', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2cf7f16a-d817-44cf-982b-eedc631ceac6' User entered '12 Aug 2020 20:34'	System	13 Aug 2020 01:35:03
	System	13 Aug 2020 01:35:03

US3812062

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:23:57', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2624c99b-e4b3-4603-a290-b27f805bac30' User entered 'None (1)'	System	06 Aug 2020 18:24:48
	System	06 Aug 2020 18:24:48

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:24:05', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2624c99b-e4b3-4603-a290-b27f805bac30' User entered 'No (N)'	System	06 Aug 2020 18:24:48
	System	06 Aug 2020 18:24:48

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:24:12', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2624c99b-e4b3-4603-a290-b27f805bac30' User entered 'No (N)'	System	06 Aug 2020 18:24:48
	System	06 Aug 2020 18:24:48

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:24:26', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2624c99b-e4b3-4603-a290-b27f805bac30' User entered 'None (1)'	System	06 Aug 2020 18:24:48
	System	06 Aug 2020 18:24:48

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:24:41', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2624c99b-e4b3-4603-a290-b27f805bac30' User entered '06 Aug 2020 13:24'	System	06 Aug 2020 18:24:48
	System	06 Aug 2020 18:24:48

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '06 Aug 2020 12:58'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '06 Aug 2020 15:28'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:04:55', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '8e54c2b1-2b0c-4912-8c66-74fff172a1b1'	System	07 Aug 2020 14:05:28
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 14:05:28

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:04:59', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '8e54c2b1-2b0c-4912-8c66-74fff172a1b1'	System	07 Aug 2020 14:05:28
User entered 'No (N)'	System	07 Aug 2020 14:05:28

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:05:04', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '8e54c2b1-2b0c-4912-8c66-74fff172a1b1'	System	07 Aug 2020 14:05:28
User entered 'No (N)'	System	07 Aug 2020 14:05:28

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:05:15', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '8e54c2b1-2b0c-4912-8c66-74fff172a1b1' User entered 'None (1)'	System	07 Aug 2020 14:05:28
	System	07 Aug 2020 14:05:28

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:05:27', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '8e54c2b1-2b0c-4912-8c66-74fff172a1b1'	System	07 Aug 2020 14:05:28
User entered '07 Aug 2020 09:05'	System	07 Aug 2020 14:05:28

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '06 Aug 2020 16:23'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 2'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:04:38', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fd795de1-15ae-4acb-90e4-4d16a3e071cc' User entered 'None (1)'	System	08 Aug 2020 00:05:07
	System	08 Aug 2020 00:05:07

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:04:42', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fd795de1-15ae-4acb-90e4-4d16a3e071cc' User entered 'No (N)'	System	08 Aug 2020 00:05:07
	System	08 Aug 2020 00:05:07

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:04:48', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fd795de1-15ae-4acb-90e4-4d16a3e071cc' User entered 'No (N)'	System	08 Aug 2020 00:05:07
	System	08 Aug 2020 00:05:07

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:04:56', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fd795de1-15ae-4acb-90e4-4d16a3e071cc' User entered 'None (1)'	System	08 Aug 2020 00:05:07
	System	08 Aug 2020 00:05:07

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:05:02', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fd795de1-15ae-4acb-90e4-4d16a3e071cc' User entered '07 Aug 2020 19:05'	System	08 Aug 2020 00:05:07
	System	08 Aug 2020 00:05:07

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 3'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:58:30', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '7236d88e-6dfb-4ce0-9b6b-823ced1bc1d7' User entered 'None (1)'	System	09 Aug 2020 01:59:02
	System	09 Aug 2020 01:59:02

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:58:38', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '7236d88e-6dfb-4ce0-9b6b-823ced1bc1d7' User entered 'No (N)'	System	09 Aug 2020 01:59:02
	System	09 Aug 2020 01:59:02

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:58:43', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '7236d88e-6dfb-4ce0-9b6b-823ced1bc1d7'	System	09 Aug 2020 01:59:02
User entered 'No (N)'	System	09 Aug 2020 01:59:02

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:58:50', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '7236d88e-6dfb-4ce0-9b6b-823ced1bc1d7'	System	09 Aug 2020 01:59:02
User entered 'None (1)'	System	09 Aug 2020 01:59:02

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:59:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '7236d88e-6dfb-4ce0-9b6b-823ced1bc1d7'	System	09 Aug 2020 01:59:02
User entered '08 Aug 2020 20:59'	System	09 Aug 2020 01:59:02

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 4'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:18:33', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd76f6c68-c0f8-4baa-b4fc-1e8bd93ce10f' User entered 'None (1)'	System	10 Aug 2020 01:18:57
	System	10 Aug 2020 01:18:57

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:18:37', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd76f6c68-c0f8-4baa-b4fc-1e8bd93ce10f' User entered 'No (N)'	System	10 Aug 2020 01:18:57
	System	10 Aug 2020 01:18:57

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:18:41', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd76f6c68-c0f8-4baa-b4fc-1e8bd93ce10f' User entered 'No (N)'	System	10 Aug 2020 01:18:57
	System	10 Aug 2020 01:18:57

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:18:45', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd76f6c68-c0f8-4baa-b4fc-1e8bd93ce10f' User entered 'None (1)'	System	10 Aug 2020 01:18:57
	System	10 Aug 2020 01:18:57

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:18:55', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd76f6c68-c0f8-4baa-b4fc-1e8bd93ce10f' User entered '09 Aug 2020 20:18'	System	10 Aug 2020 01:18:57
	System	10 Aug 2020 01:18:57

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 5'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:06:19', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'e95537df-2e68-4553-9aec-0e2a677b1171'	System	11 Aug 2020 00:06:57
User entered 'None (1)'	System	11 Aug 2020 00:06:57

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:06:24', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'e95537df-2e68-4553-9aec-0e2a677b1171' User entered 'No (N)'	System	11 Aug 2020 00:06:57
	System	11 Aug 2020 00:06:57

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:06:28', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'e95537df-2e68-4553-9aec-0e2a677b1171'	System	11 Aug 2020 00:06:57
User entered 'No (N)'	System	11 Aug 2020 00:06:57

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:06:45', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'e95537df-2e68-4553-9aec-0e2a677b1171'	System	11 Aug 2020 00:06:57
User entered 'None (1)'	System	11 Aug 2020 00:06:57

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:06:51', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'e95537df-2e68-4553-9aec-0e2a677b1171' User entered '10 Aug 2020 19:06'	System	11 Aug 2020 00:06:57
	System	11 Aug 2020 00:06:57

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 6'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:08:20', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'e5ddbe90-dcb5-44e9-ada3-36d427f6f3a0'	System	12 Aug 2020 00:08:56
User entered 'None (1)'	System	12 Aug 2020 00:08:56

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:08:25', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'e5ddbe90-dcb5-44e9-ada3-36d427f6f3a0'	System	12 Aug 2020 00:08:56
User entered 'No (N)'	System	12 Aug 2020 00:08:56

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:08:31', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'e5ddbe90-dcb5-44e9-ada3-36d427f6f3a0' User entered 'No (N)'	System	12 Aug 2020 00:08:56
	System	12 Aug 2020 00:08:56

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:08:47', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'e5ddbe90-dcb5-44e9-ada3-36d427f6f3a0' User entered 'None (1)'	System	12 Aug 2020 00:08:56
	System	12 Aug 2020 00:08:56

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:08:54', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'e5ddbe90-dcb5-44e9-ada3-36d427f6f3a0' User entered '11 Aug 2020 19:08'	System	12 Aug 2020 00:08:56
	System	12 Aug 2020 00:08:56

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 7'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:35:10', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3e268074-f107-4bfb-b66d-67dc99ebbdfe' User entered 'None (1)'	System	13 Aug 2020 01:35:37
	System	13 Aug 2020 01:35:37

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:35:15', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3e268074-f107-4bfb-b66d-67dc99ebbdfe' User entered 'No (N)'	System	13 Aug 2020 01:35:37
	System	13 Aug 2020 01:35:37

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:35:19', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3e268074-f107-4bfb-b66d-67dc99ebbdfe' User entered 'No (N)'	System	13 Aug 2020 01:35:37
	System	13 Aug 2020 01:35:37

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:35:29', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3e268074-f107-4bfb-b66d-67dc99ebbdfe' User entered 'None (1)'	System	13 Aug 2020 01:35:37
	System	13 Aug 2020 01:35:37

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:35:35', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3e268074-f107-4bfb-b66d-67dc99ebbdfe' User entered '12 Aug 2020 20:35'	System	13 Aug 2020 01:35:37
	System	13 Aug 2020 01:35:37

US3812062

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:24:49', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'afd16d02-8e5c-4baa-9c2a-64f96f237faf' User entered 'None (0)'	System	06 Aug 2020 18:25:22
	System	06 Aug 2020 18:25:22

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:24:53', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'afd16d02-8e5c-4baa-9c2a-64f96f237faf' User entered 'None (0)'	System	06 Aug 2020 18:25:22
	System	06 Aug 2020 18:25:22

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:24:57', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'afd16d02-8e5c-4baa-9c2a-64f96f237faf' User entered 'None (0)'	System	06 Aug 2020 18:25:22
	System	06 Aug 2020 18:25:22

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:25:03', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'afd16d02-8e5c-4baa-9c2a-64f96f237faf' User entered 'None (0)'	System	06 Aug 2020 18:25:22
	System	06 Aug 2020 18:25:22

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:25:07', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'afd16d02-8e5c-4baa-9c2a-64f96f237faf' User entered 'None (0)'	System	06 Aug 2020 18:25:22
	System	06 Aug 2020 18:25:22

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:25:10', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'afd16d02-8e5c-4baa-9c2a-64f96f237faf' User entered 'None (0)'	System	06 Aug 2020 18:25:22
	System	06 Aug 2020 18:25:22

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:25:16', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'afd16d02-8e5c-4baa-9c2a-64f96f237faf' User entered 'No (N)'	System	06 Aug 2020 18:25:22
	System	06 Aug 2020 18:25:22

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-06T13:25:19', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'afd16d02-8e5c-4baa-9c2a-64f96f237faf' User entered '06 Aug 2020 13:25'	System	06 Aug 2020 18:25:22
	System	06 Aug 2020 18:25:22

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '06 Aug 2020 12:58'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '06 Aug 2020 15:28'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:05:40', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3a7dafb1-6142-41f1-832a-223dca080856' User entered 'None (0)'	System	07 Aug 2020 14:06:23
	System	07 Aug 2020 14:06:23

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:05:45', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3a7dafb1-6142-41f1-832a-223dca080856' User entered 'None (0)'	System	07 Aug 2020 14:06:23
	System	07 Aug 2020 14:06:23

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:05:53', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3a7dafb1-6142-41f1-832a-223dca080856' User entered 'None (0)'	System	07 Aug 2020 14:06:23
	System	07 Aug 2020 14:06:23

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:05:59', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3a7dafb1-6142-41f1-832a-223dca080856' User entered 'None (0)'	System	07 Aug 2020 14:06:23
	System	07 Aug 2020 14:06:23

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:06:03', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3a7dafb1-6142-41f1-832a-223dca080856' User entered 'None (0)'	System	07 Aug 2020 14:06:23
	System	07 Aug 2020 14:06:23

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:06:07', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3a7dafb1-6142-41f1-832a-223dca080856' User entered 'None (0)'	System	07 Aug 2020 14:06:23
	System	07 Aug 2020 14:06:23

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:06:13', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3a7dafb1-6142-41f1-832a-223dca080856'	System	07 Aug 2020 14:06:23
User entered 'No (N)'	System	07 Aug 2020 14:06:23

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T09:06:20', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3a7dafb1-6142-41f1-832a-223dca080856' User entered '07 Aug 2020 09:06'	System	07 Aug 2020 14:06:23
	System	07 Aug 2020 14:06:23

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '06 Aug 2020 16:23'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 2'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:05:09', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '1b65e748-ff3b-4704-a84e-8579000d754f' User entered 'None (0)'	System	08 Aug 2020 00:06:03
	System	08 Aug 2020 00:06:03

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:05:14', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '1b65e748-ff3b-4704-a84e-8579000d754f' User entered 'None (0)'	System	08 Aug 2020 00:06:03
	System	08 Aug 2020 00:06:03

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:05:23', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '1b65e748-ff3b-4704-a84e-8579000d754f' User entered 'None (0)'	System	08 Aug 2020 00:06:03
	System	08 Aug 2020 00:06:03

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:05:34', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '1b65e748-ff3b-4704-a84e-8579000d754f' User entered 'None (0)'	System	08 Aug 2020 00:06:03
	System	08 Aug 2020 00:06:03

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:05:37', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '1b65e748-ff3b-4704-a84e-8579000d754f' User entered 'None (0)'	System	08 Aug 2020 00:06:03
	System	08 Aug 2020 00:06:03

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:05:41', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '1b65e748-ff3b-4704-a84e-8579000d754f' User entered 'None (0)'	System	08 Aug 2020 00:06:03
	System	08 Aug 2020 00:06:03

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:05:48', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '1b65e748-ff3b-4704-a84e-8579000d754f' User entered 'No (N)'	System	08 Aug 2020 00:06:03
	System	08 Aug 2020 00:06:03

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-07T19:05:56', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '1b65e748-ff3b-4704-a84e-8579000d754f' User entered '07 Aug 2020 19:05'	System	08 Aug 2020 00:06:03
	System	08 Aug 2020 00:06:03

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 3'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:59:08', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2614c6e1-1cd1-4c13-80a0-3fb831f67a6a' User entered 'None (0)'	System	09 Aug 2020 02:00:02
	System	09 Aug 2020 02:00:02

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:59:12', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2614c6e1-1cd1-4c13-80a0-3fb831f67a6a' User entered 'None (0)'	System	09 Aug 2020 02:00:02
	System	09 Aug 2020 02:00:02

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:59:20', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2614c6e1-1cd1-4c13-80a0-3fb831f67a6a' User entered 'None (0)'	System	09 Aug 2020 02:00:02
	System	09 Aug 2020 02:00:02

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:59:27', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2614c6e1-1cd1-4c13-80a0-3fb831f67a6a' User entered 'None (0)'	System	09 Aug 2020 02:00:02
	System	09 Aug 2020 02:00:02

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:42**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:59:31', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2614c6e1-1cd1-4c13-80a0-3fb831f67a6a' User entered 'None (0)'	System	09 Aug 2020 02:00:02
	System	09 Aug 2020 02:00:02

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:59:35', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2614c6e1-1cd1-4c13-80a0-3fb831f67a6a' User entered 'None (0)'	System	09 Aug 2020 02:00:02
	System	09 Aug 2020 02:00:02

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:59:45', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2614c6e1-1cd1-4c13-80a0-3fb831f67a6a' User entered 'No (N)'	System	09 Aug 2020 02:00:02
	System	09 Aug 2020 02:00:02

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-08T20:59:59', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2614c6e1-1cd1-4c13-80a0-3fb831f67a6a' User entered '08 Aug 2020 20:59'	System	09 Aug 2020 02:00:02
	System	09 Aug 2020 02:00:02

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 4'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:19:02', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd4d56b9c-5eb2-4173-9a90-0e8e2aa80f98' User entered 'None (0)'	System	10 Aug 2020 01:19:37
	System	10 Aug 2020 01:19:37

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:42**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:19:06', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd4d56b9c-5eb2-4173-9a90-0e8e2aa80f98' User entered 'None (0)'	System	10 Aug 2020 01:19:37
	System	10 Aug 2020 01:19:37

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:19:11', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd4d56b9c-5eb2-4173-9a90-0e8e2aa80f98' User entered 'None (0)'	System	10 Aug 2020 01:19:37
	System	10 Aug 2020 01:19:37

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:19:15', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd4d56b9c-5eb2-4173-9a90-0e8e2aa80f98' User entered 'None (0)'	System	10 Aug 2020 01:19:37
	System	10 Aug 2020 01:19:37

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:19:18', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd4d56b9c-5eb2-4173-9a90-0e8e2aa80f98' User entered 'None (0)'	System	10 Aug 2020 01:19:37
	System	10 Aug 2020 01:19:37

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:19:21', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd4d56b9c-5eb2-4173-9a90-0e8e2aa80f98' User entered 'None (0)'	System	10 Aug 2020 01:19:37
	System	10 Aug 2020 01:19:37

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:19:29', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd4d56b9c-5eb2-4173-9a90-0e8e2aa80f98'	System	10 Aug 2020 01:19:37
User entered 'No (N)'	System	10 Aug 2020 01:19:37

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-09T20:19:33', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd4d56b9c-5eb2-4173-9a90-0e8e2aa80f98'	System	10 Aug 2020 01:19:37
User entered '09 Aug 2020 20:19'	System	10 Aug 2020 01:19:37

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 5'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:42**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:06:57', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '537b9133-ed90-4f44-8e5e-33a0d45ac913' User entered 'None (0)'	System	11 Aug 2020 00:07:35
	System	11 Aug 2020 00:07:35

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:42**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:07:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '537b9133-ed90-4f44-8e5e-33a0d45ac913' User entered 'None (0)'	System	11 Aug 2020 00:07:35
	System	11 Aug 2020 00:07:35

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:07:05', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '537b9133-ed90-4f44-8e5e-33a0d45ac913' User entered 'None (0)'	System	11 Aug 2020 00:07:35
	System	11 Aug 2020 00:07:35

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:07:09', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '537b9133-ed90-4f44-8e5e-33a0d45ac913' User entered 'None (0)'	System	11 Aug 2020 00:07:35
	System	11 Aug 2020 00:07:35

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:07:13', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '537b9133-ed90-4f44-8e5e-33a0d45ac913' User entered 'None (0)'	System	11 Aug 2020 00:07:35
	System	11 Aug 2020 00:07:35

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:07:16', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '537b9133-ed90-4f44-8e5e-33a0d45ac913' User entered 'None (0)'	System	11 Aug 2020 00:07:35
	System	11 Aug 2020 00:07:35

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:07:24', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '537b9133-ed90-4f44-8e5e-33a0d45ac913'	System	11 Aug 2020 00:07:35
User entered 'No (N)'	System	11 Aug 2020 00:07:35

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-10T19:07:29', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '537b9133-ed90-4f44-8e5e-33a0d45ac913' User entered '10 Aug 2020 19:07'	System	11 Aug 2020 00:07:35
	System	11 Aug 2020 00:07:35

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 6'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:09:01', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6a297896-883e-4794-b9b7-c31cb9975b80' User entered 'None (0)'	System	12 Aug 2020 00:09:49
	System	12 Aug 2020 00:09:49

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:09:13', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6a297896-883e-4794-b9b7-c31cb9975b80' User entered 'None (0)'	System	12 Aug 2020 00:09:49
	System	12 Aug 2020 00:09:49

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:09:17', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6a297896-883e-4794-b9b7-c31cb9975b80' User entered 'None (0)'	System	12 Aug 2020 00:09:49
	System	12 Aug 2020 00:09:49

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:09:23', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6a297896-883e-4794-b9b7-c31cb9975b80' User entered 'None (0)'	System	12 Aug 2020 00:09:49
	System	12 Aug 2020 00:09:49

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:09:28', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6a297896-883e-4794-b9b7-c31cb9975b80' User entered 'None (0)'	System	12 Aug 2020 00:09:49
	System	12 Aug 2020 00:09:49

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:09:32', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6a297896-883e-4794-b9b7-c31cb9975b80' User entered 'None (0)'	System	12 Aug 2020 00:09:49
	System	12 Aug 2020 00:09:49

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:09:38', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6a297896-883e-4794-b9b7-c31cb9975b80'	System	12 Aug 2020 00:09:49
User entered 'No (N)'	System	12 Aug 2020 00:09:49

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-11T19:09:44', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6a297896-883e-4794-b9b7-c31cb9975b80'	System	12 Aug 2020 00:09:49
User entered '11 Aug 2020 19:09'	System	12 Aug 2020 00:09:49

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 7'	System	06 Aug 2020 17:51:09

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:35:41', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'bf11f701-77e0-4c5d-9317-07af819b2253'	System	13 Aug 2020 01:36:20
User entered 'None (0)'	System	13 Aug 2020 01:36:20

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:35:47', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'bf11f701-77e0-4c5d-9317-07af819b2253' User entered 'None (0)'	System	13 Aug 2020 01:36:20
	System	13 Aug 2020 01:36:20

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:35:52', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'bf11f701-77e0-4c5d-9317-07af819b2253' User entered 'None (0)'	System	13 Aug 2020 01:36:20
	System	13 Aug 2020 01:36:20

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:36:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'bf11f701-77e0-4c5d-9317-07af819b2253' User entered 'None (0)'	System	13 Aug 2020 01:36:20
	System	13 Aug 2020 01:36:20

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:36:05', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'bf11f701-77e0-4c5d-9317-07af819b2253' User entered 'None (0)'	System	13 Aug 2020 01:36:20
	System	13 Aug 2020 01:36:20

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:36:08', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'bf11f701-77e0-4c5d-9317-07af819b2253' User entered 'None (0)'	System	13 Aug 2020 01:36:20
	System	13 Aug 2020 01:36:20

US3812062

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:36:13', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'bf11f701-77e0-4c5d-9317-07af819b2253'	System	13 Aug 2020 01:36:20
User entered 'No (N)'	System	13 Aug 2020 01:36:20

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-08-12T20:36:17', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'bf11f701-77e0-4c5d-9317-07af819b2253'	System	13 Aug 2020 01:36:20
User entered '12 Aug 2020 20:36'	System	13 Aug 2020 01:36:20

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:31
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Aug 2020 20:44:25

**US3812062**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '13 Aug 2020'	Breanna Galibert (b) (4)	13 Aug 2020 20:44:25

US3812062

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	13 Aug 2020 20:44:25

US3812062

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	13 Aug 2020 20:44:25

US3812062

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	25 Aug 2020 22:33:46

**US3812062**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'I'	System	25 Aug 2020 22:33:46

**US3812062**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	25 Aug 2020 22:33:56

**US3812062**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '20 Aug 2020'	Breanna Galibert (b) (4)	25 Aug 2020 22:33:56

**US3812062**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	25 Aug 2020 22:33:56

**US3812062**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	25 Aug 2020 22:33:56

US3812062

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	03 Sep 2020 12:40:08

**US3812062**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'I'	System	03 Sep 2020 12:40:08

**US3812062**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Sep 2020 17:59:58

**US3812062**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '27 Aug 2020'	Breanna Galibert (b) (4)	11 Sep 2020 17:59:58

**US3812062**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	11 Sep 2020 17:59:58

**US3812062**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	11 Sep 2020 17:59:58

US3812062

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Sep 2020 22:23:56

**US3812062**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'I'	System	04 Sep 2020 22:23:56

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Sep 2020 22:24:06

US3812062

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:16:51
User entered '4 Sep 2020'	(b) (4)	
	Breanna Galibert (b) (4)	04 Sep 2020 22:24:06
	(b) (4)	

US3812062

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	04 Sep 2020 22:24:06

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'VISIT2'	System	04 Sep 2020 22:24:06

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:17:00
User entered '4 Sep 2020'	(b) (4)	
	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54
	(b) (4)	

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '15:45'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered '04 Sep 2020 15:45'	System	11 Nov 2020 16:17:00
User entered '4 Sep 2020 15:45'	System	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '98.1' F	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '60'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'bpm'	System	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '14'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'breaths/min'	System	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '110'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'mmHg'	System	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '68'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:53:42

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'mmHg'	System	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:17:00
User entered '4 Sep 2020'	(b) (4)	
	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '17:31'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered '04 Sep 2020 17:31'	System	11 Nov 2020 16:17:00
User entered '4 Sep 2020 17:31'	System	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:48:29
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	Anya Penly (b) (4) (b) (4)	18 Sep 2020 21:49:49
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:45:50
User entered '96.2' F	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '56'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'bpm'	System	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '14'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'breaths/min'	System	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '122'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'mmHg'	System	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '82'	Breanna Galibert (b) (4)	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:53:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'mmHg'	System	11 Sep 2020 18:01:54

US3812062

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Sep 2020 18:00:13

US3812062

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	11 Sep 2020 18:00:13

US3812062

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Sep 2020 22:24:38

US3812062

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	04 Sep 2020 22:24:38

US3812062

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

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 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	04 Sep 2020 22:24:38

US3812062

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 22:24:38

US3812062

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:17:11
User entered '4 Sep 2020'	(b) (4)	
	Breanna Galibert (b) (4)	04 Sep 2020 22:24:38
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '16:50'	Breanna Galibert (b) (4)	04 Sep 2020 22:24:38

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:53:42**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered '04 Sep 2020 16:50'	System	11 Nov 2020 16:17:11
User entered '4 Sep 2020 16:50'	System	04 Sep 2020 22:24:38

US3812062

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4)	04 Sep 2020 22:24:38

US3812062

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'ONCE'	System	04 Sep 2020 22:24:38

US3812062

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:53:42

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 22:24:38

US3812062

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Sep 2020 18:00:27

US3812062

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:17:18
User entered '4 Sep 2020'	(b) (4)	
	Breanna Galibert (b) (4)	11 Sep 2020 18:00:27
	(b) (4)	

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:42**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '16:15'	Breanna Galibert (b) (4)	11 Sep 2020 18:00:27

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered '04 Sep 2020 16:15'	System	11 Nov 2020 16:17:18
User entered '4 Sep 2020 16:15'	System	11 Sep 2020 18:00:27

US3812062

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:53:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '04 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:17:23
User entered '4 Sep 2020'	(b) (4)	
	Breanna Galibert (b) (4)	11 Sep 2020 18:00:42
	(b) (4)	

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:00:42

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Sep 2020 18:00:42

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:53:42**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '16:19'	Breanna Galibert (b) (4)	11 Sep 2020 18:00:42

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered '04 Sep 2020 16:19'	System	11 Nov 2020 16:17:23
User entered '4 Sep 2020 16:19'	System	11 Sep 2020 18:00:42

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4) (b) (4)	11 Sep 2020 18:00:42

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Sep 2020 18:00:42

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:53:42**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	11 Sep 2020 18:00:42

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered empty.	System	11 Sep 2020 18:00:42

US3812062

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	11 Sep 2020 21:26:56

**US3812062**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'I'	System	11 Sep 2020 21:26:56

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:24:59', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd82f2052-6643-45f6-9c67-1ae9b6caa7f5' User entered 'Yes (Y)'	System	04 Sep 2020 22:25:57
	System	04 Sep 2020 22:25:57

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:25:26', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd82f2052-6643-45f6-9c67-1ae9b6caa7f5' User entered '96.2'	System	04 Sep 2020 22:25:57
	System	04 Sep 2020 22:25:57

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:25:36', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd82f2052-6643-45f6-9c67-1ae9b6caa7f5'	System	04 Sep 2020 22:25:57
User entered 'Yes (Y)'	System	04 Sep 2020 22:25:57

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject was contacted' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 08:59:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Karen Knapp (b) (4)	14 Sep 2020 12:54:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:25:46', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd82f2052-6643-45f6-9c67-1ae9b6caa7f5'	(b) (4)	
User entered '1'	System	04 Sep 2020 22:25:57
	System	04 Sep 2020 22:25:57
	System	04 Sep 2020 22:25:57

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:25:46', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd82f2052-6643-45f6-9c67-1ae9b6caa7f5' User entered '0'	System	04 Sep 2020 22:25:57
	System	04 Sep 2020 22:25:57

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:25:56', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd82f2052-6643-45f6-9c67-1ae9b6caa7f5' User entered '04 Sep 2020 17:25'	System	04 Sep 2020 22:25:57
	System	04 Sep 2020 22:25:57

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '04 Sep 2020 17:10'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '04 Sep 2020 19:40'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:46:38', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '27abe0e2-b5d4-4418-920f-bacd24db1fe3' User entered 'Yes (Y)'	System	05 Sep 2020 02:47:30
	System	05 Sep 2020 02:47:30

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:46:49', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '27abe0e2-b5d4-4418-920f-bacd24db1fe3' User entered '96.3'	System	05 Sep 2020 02:47:30
	System	05 Sep 2020 02:47:30

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:47:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '27abe0e2-b5d4-4418-920f-bacd24db1fe3'	System	05 Sep 2020 02:47:30
User entered 'Yes (Y)'	System	05 Sep 2020 02:47:30

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject was contacted' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 08:59:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Karen Knapp (b) (4)	14 Sep 2020 12:54:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:47:14', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '27abe0e2-b5d4-4418-920f-bacd24db1fe3'	(b) (4)	
User entered '1'	System	05 Sep 2020 02:47:30
	System	05 Sep 2020 02:47:30
	System	05 Sep 2020 02:47:30

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:47:14', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '27abe0e2-b5d4-4418-920f-bacd24db1fe3' User entered '0'	System	05 Sep 2020 02:47:30
	System	05 Sep 2020 02:47:30

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:47:20', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '27abe0e2-b5d4-4418-920f-bacd24db1fe3' User entered '04 Sep 2020 21:47'	System	05 Sep 2020 02:47:30
	System	05 Sep 2020 02:47:30

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '04 Sep 2020 20:35'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 2'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 3'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:18:55', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'dab7f900-f532-463b-9953-2555ca3100b9' User entered 'Yes (Y)'	System	07 Sep 2020 11:19:32
	System	07 Sep 2020 11:19:32

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:19:07', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'dab7f900-f532-463b-9953-2555ca3100b9' User entered '96.6'	System	07 Sep 2020 11:19:32
	System	07 Sep 2020 11:19:32

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:19:19', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'dab7f900-f532-463b-9953-2555ca3100b9' User entered 'No (N)'	System	07 Sep 2020 11:19:32
	System	07 Sep 2020 11:19:32

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:19:28', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'dab7f900-f532-463b-9953-2555ca3100b9' User entered '07 Sep 2020 06:19'	System	07 Sep 2020 11:19:32
	System	07 Sep 2020 11:19:32

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 4'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:16:12', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fe106d50-2484-4df2-a1b4-bbfae33f5cc4' User entered 'Yes (Y)'	System	08 Sep 2020 14:16:42
	System	08 Sep 2020 14:16:42

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:16:22', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fe106d50-2484-4df2-a1b4-bbfae33f5cc4' User entered '96.8'	System	08 Sep 2020 14:16:42
	System	08 Sep 2020 14:16:42

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:16:33', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fe106d50-2484-4df2-a1b4-bbfae33f5cc4'	System	08 Sep 2020 14:16:42
User entered 'No (N)'	System	08 Sep 2020 14:16:42

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:16:40', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fe106d50-2484-4df2-a1b4-bbfae33f5cc4' User entered '08 Sep 2020 09:16'	System	08 Sep 2020 14:16:42
	System	08 Sep 2020 14:16:42

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 5'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:30:22', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2b075fee-4dfd-4e92-90be-9e606eaf4ac5' User entered 'Yes (Y)'	System	09 Sep 2020 01:30:47
	System	09 Sep 2020 01:30:47

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:30:28', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2b075fee-4dfd-4e92-90be-9e606eaf4ac5' User entered '96.3'	System	09 Sep 2020 01:30:47
	System	09 Sep 2020 01:30:47

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:30:36', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2b075fee-4dfd-4e92-90be-9e606eaf4ac5'	System	09 Sep 2020 01:30:47
User entered 'No (N)'	System	09 Sep 2020 01:30:47

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:30:41', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2b075fee-4dfd-4e92-90be-9e606eaf4ac5'	System	09 Sep 2020 01:30:47
User entered '08 Sep 2020 20:30'	System	09 Sep 2020 01:30:47

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 6'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:41:10', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '8e1a9a78-bb01-4516-8a2d-d8b1cded959e' User entered 'Yes (Y)'	System	10 Sep 2020 10:41:52
	System	10 Sep 2020 10:41:52

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:41:30', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '8e1a9a78-bb01-4516-8a2d-d8b1cded959e' User entered '98.1'	System	10 Sep 2020 10:41:52
	System	10 Sep 2020 10:41:52

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:41:41', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '8e1a9a78-bb01-4516-8a2d-d8b1cded959e' User entered 'No (N)'	System	10 Sep 2020 10:41:52
	System	10 Sep 2020 10:41:52

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:41:50', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '8e1a9a78-bb01-4516-8a2d-d8b1cded959e' User entered '10 Sep 2020 05:41'	System	10 Sep 2020 10:41:52
	System	10 Sep 2020 10:41:52

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 7'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:42

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:17:19', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4a55aca4-b7db-4bed-89ec-ece7a70a3654' User entered 'Yes (Y)'	System	10 Sep 2020 21:18:11
	System	10 Sep 2020 21:18:11

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:42

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:17:36', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4a55aca4-b7db-4bed-89ec-ece7a70a3654' User entered '96.3'	System	10 Sep 2020 21:18:11
	System	10 Sep 2020 21:18:11

US3812062

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:17:48', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4a55aca4-b7db-4bed-89ec-ece7a70a3654' User entered 'No (N)'	System	10 Sep 2020 21:18:11
	System	10 Sep 2020 21:18:11

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:17:57', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4a55aca4-b7db-4bed-89ec-ece7a70a3654' User entered '10 Sep 2020 16:17'	System	10 Sep 2020 21:18:11
	System	10 Sep 2020 21:18:11

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:26:15', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '76e091cb-cc5c-4be3-83fb-3ceacbd4a2f4' User entered 'None (1)'	System	04 Sep 2020 22:26:44
	System	04 Sep 2020 22:26:44

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:26:21', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '76e091cb-cc5c-4be3-83fb-3ceacbd4a2f4' User entered 'No (N)'	System	04 Sep 2020 22:26:44
	System	04 Sep 2020 22:26:44

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:26:26', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '76e091cb-cc5c-4be3-83fb-3ceacbd4a2f4' User entered 'No (N)'	System	04 Sep 2020 22:26:44
	System	04 Sep 2020 22:26:44

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:26:35', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '76e091cb-cc5c-4be3-83fb-3ceacbd4a2f4' User entered 'None (1)'	System	04 Sep 2020 22:26:44
	System	04 Sep 2020 22:26:44

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:26:41', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '76e091cb-cc5c-4be3-83fb-3ceacbd4a2f4' User entered '04 Sep 2020 17:26'	System	04 Sep 2020 22:26:44
	System	04 Sep 2020 22:26:44

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '04 Sep 2020 17:10'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '04 Sep 2020 19:40'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:47:36', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'bfed8f49-ee3e-4fff-8725-0683019975cd'	System	05 Sep 2020 02:48:06
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 02:48:06

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:47:41', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'bfed8f49-ee3e-4fff-8725-0683019975cd' User entered 'No (N)'	System	05 Sep 2020 02:48:06
	System	05 Sep 2020 02:48:06

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:47:45', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'bfed8f49-ee3e-4fff-8725-0683019975cd' User entered 'No (N)'	System	05 Sep 2020 02:48:06
	System	05 Sep 2020 02:48:06

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:47:56', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'bfed8f49-ee3e-4fff-8725-0683019975cd' User entered 'None (1)'	System	05 Sep 2020 02:48:06
	System	05 Sep 2020 02:48:06

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:48:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'bfed8f49-ee3e-4fff-8725-0683019975cd' User entered '04 Sep 2020 21:48'	System	05 Sep 2020 02:48:06
	System	05 Sep 2020 02:48:06

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '04 Sep 2020 20:35'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 2'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 3'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:20:11', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6e146b73-28f5-419b-8bb5-b8296d9c0703'	System	07 Sep 2020 11:20:23
User entered 'None (1)'	System	07 Sep 2020 11:20:23

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:19:42', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6e146b73-28f5-419b-8bb5-b8296d9c0703' User entered 'No (N)'	System	07 Sep 2020 11:20:23
	System	07 Sep 2020 11:20:23

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:19:48', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6e146b73-28f5-419b-8bb5-b8296d9c0703'	System	07 Sep 2020 11:20:23
User entered 'No (N)'	System	07 Sep 2020 11:20:23

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:19:55', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6e146b73-28f5-419b-8bb5-b8296d9c0703'	System	07 Sep 2020 11:20:23
User entered 'None (1)'	System	07 Sep 2020 11:20:23

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:20:17', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6e146b73-28f5-419b-8bb5-b8296d9c0703' User entered '07 Sep 2020 06:20'	System	07 Sep 2020 11:20:23
	System	07 Sep 2020 11:20:23

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 4'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:16:50', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '1b60b25e-fab1-4c4f-906a-13ce92aaab81'	System	08 Sep 2020 14:17:19
User entered 'None (1)'	System	08 Sep 2020 14:17:19

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:16:56', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '1b60b25e-fab1-4c4f-906a-13ce92aaab81' User entered 'No (N)'	System	08 Sep 2020 14:17:19
	System	08 Sep 2020 14:17:19

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:17:05', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '1b60b25e-fab1-4c4f-906a-13ce92aaab81' User entered 'No (N)'	System	08 Sep 2020 14:17:19
	System	08 Sep 2020 14:17:19

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:17:10', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '1b60b25e-fab1-4c4f-906a-13ce92aaab81'	System	08 Sep 2020 14:17:19
User entered 'None (1)'	System	08 Sep 2020 14:17:19

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:17:17', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '1b60b25e-fab1-4c4f-906a-13ce92aaab81' User entered '08 Sep 2020 09:17'	System	08 Sep 2020 14:17:19
	System	08 Sep 2020 14:17:19

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 5'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:30:48', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3a88de78-c015-4245-b838-8c3c9f4719e8' User entered 'None (1)'	System	09 Sep 2020 01:31:15
	System	09 Sep 2020 01:31:15

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:30:53', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3a88de78-c015-4245-b838-8c3c9f4719e8' User entered 'No (N)'	System	09 Sep 2020 01:31:15
	System	09 Sep 2020 01:31:15

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:30:58', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3a88de78-c015-4245-b838-8c3c9f4719e8' User entered 'No (N)'	System	09 Sep 2020 01:31:15
	System	09 Sep 2020 01:31:15

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:31:07', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3a88de78-c015-4245-b838-8c3c9f4719e8' User entered 'None (1)'	System	09 Sep 2020 01:31:15
	System	09 Sep 2020 01:31:15

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:31:11', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '3a88de78-c015-4245-b838-8c3c9f4719e8' User entered '08 Sep 2020 20:31'	System	09 Sep 2020 01:31:15
	System	09 Sep 2020 01:31:15

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:53:42

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 6'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:42:06', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4a09ec78-4212-476b-add0-0c0c4e5f344b'	System	10 Sep 2020 10:43:01
User entered 'None (1)'	System	10 Sep 2020 10:43:01

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:42:10', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4a09ec78-4212-476b-add0-0c0c4e5f344b' User entered 'No (N)'	System	10 Sep 2020 10:43:01
	System	10 Sep 2020 10:43:01

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:42:14', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4a09ec78-4212-476b-add0-0c0c4e5f344b' User entered 'No (N)'	System	10 Sep 2020 10:43:01
	System	10 Sep 2020 10:43:01

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:42:47', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4a09ec78-4212-476b-add0-0c0c4e5f344b'	System	10 Sep 2020 10:43:01
User entered 'None (1)'	System	10 Sep 2020 10:43:01

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:42:55', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4a09ec78-4212-476b-add0-0c0c4e5f344b' User entered '10 Sep 2020 05:42'	System	10 Sep 2020 10:43:01
	System	10 Sep 2020 10:43:01

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 7'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:18:03', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '97bb52ee-6b4b-4293-889e-f7545f0c1fa2'	System	10 Sep 2020 21:18:45
User entered 'None (1)'	System	10 Sep 2020 21:18:45

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:18:09', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '97bb52ee-6b4b-4293-889e-f7545f0c1fa2'	System	10 Sep 2020 21:18:45
User entered 'No (N)'	System	10 Sep 2020 21:18:45

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:18:14', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '97bb52ee-6b4b-4293-889e-f7545f0c1fa2'	System	10 Sep 2020 21:18:45
User entered 'No (N)'	System	10 Sep 2020 21:18:45

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:18:26', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '97bb52ee-6b4b-4293-889e-f7545f0c1fa2'	System	10 Sep 2020 21:18:45
User entered 'None (1)'	System	10 Sep 2020 21:18:45

US3812062

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:53:42

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:18:39', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '97bb52ee-6b4b-4293-889e-f7545f0c1fa2'	System	10 Sep 2020 21:18:45
User entered '10 Sep 2020 16:18'	System	10 Sep 2020 21:18:45

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:26:48', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '54452073-0676-4eb8-b35f-21d79bf56455' User entered 'None (0)'	System	04 Sep 2020 22:27:22
	System	04 Sep 2020 22:27:22

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:26:52', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '54452073-0676-4eb8-b35f-21d79bf56455' User entered 'None (0)'	System	04 Sep 2020 22:27:22
	System	04 Sep 2020 22:27:22

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:26:56', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '54452073-0676-4eb8-b35f-21d79bf56455' User entered 'None (0)'	System	04 Sep 2020 22:27:22
	System	04 Sep 2020 22:27:22

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:27:01', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '54452073-0676-4eb8-b35f-21d79bf56455' User entered 'None (0)'	System	04 Sep 2020 22:27:22
	System	04 Sep 2020 22:27:22

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:27:06', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '54452073-0676-4eb8-b35f-21d79bf56455' User entered 'None (0)'	System	04 Sep 2020 22:27:22
	System	04 Sep 2020 22:27:22

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:27:09', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '54452073-0676-4eb8-b35f-21d79bf56455' User entered 'None (0)'	System	04 Sep 2020 22:27:22
	System	04 Sep 2020 22:27:22

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:27:17', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '54452073-0676-4eb8-b35f-21d79bf56455' User entered 'No (N)'	System	04 Sep 2020 22:27:22
	System	04 Sep 2020 22:27:22

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5C53051-3EF8-43F9-A13B-BECF2B4221D2)', Time: '2020-09-04T17:27:21', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '54452073-0676-4eb8-b35f-21d79bf56455' User entered '04 Sep 2020 17:27'	System	04 Sep 2020 22:27:22
	System	04 Sep 2020 22:27:22

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '04 Sep 2020 17:10'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '04 Sep 2020 19:40'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:42**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:48:16', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2ac63215-eb1c-4a8d-b7bb-c72e1ab9364f' User entered 'None (0)'	System	05 Sep 2020 02:49:07
	System	05 Sep 2020 02:49:07

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:48:21', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2ac63215-eb1c-4a8d-b7bb-c72e1ab9364f' User entered 'None (0)'	System	05 Sep 2020 02:49:07
	System	05 Sep 2020 02:49:07

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:48:28', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2ac63215-eb1c-4a8d-b7bb-c72e1ab9364f' User entered 'None (0)'	System	05 Sep 2020 02:49:07
	System	05 Sep 2020 02:49:07

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:48:33', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2ac63215-eb1c-4a8d-b7bb-c72e1ab9364f' User entered 'None (0)'	System	05 Sep 2020 02:49:07
	System	05 Sep 2020 02:49:07

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:48:37', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2ac63215-eb1c-4a8d-b7bb-c72e1ab9364f' User entered 'None (0)'	System	05 Sep 2020 02:49:07
	System	05 Sep 2020 02:49:07

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:48:40', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2ac63215-eb1c-4a8d-b7bb-c72e1ab9364f' User entered 'None (0)'	System	05 Sep 2020 02:49:07
	System	05 Sep 2020 02:49:07

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:48:58', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2ac63215-eb1c-4a8d-b7bb-c72e1ab9364f' User entered 'No (N)'	System	05 Sep 2020 02:49:07
	System	05 Sep 2020 02:49:07

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-04T21:49:02', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2ac63215-eb1c-4a8d-b7bb-c72e1ab9364f' User entered '04 Sep 2020 21:49'	System	05 Sep 2020 02:49:07
	System	05 Sep 2020 02:49:07

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:53:42

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '04 Sep 2020 20:35'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 2'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:53:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:32

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:53:42

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 3'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:20:44', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fa1558f6-1a45-43d6-9e5c-735a0bcb2843' User entered 'None (0)'	System	07 Sep 2020 11:21:22
	System	07 Sep 2020 11:21:22

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:42**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:20:49', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fa1558f6-1a45-43d6-9e5c-735a0bcb2843' User entered 'None (0)'	System	07 Sep 2020 11:21:22
	System	07 Sep 2020 11:21:22

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:20:54', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fa1558f6-1a45-43d6-9e5c-735a0bcb2843' User entered 'None (0)'	System	07 Sep 2020 11:21:22
	System	07 Sep 2020 11:21:22

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:20:58', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fa1558f6-1a45-43d6-9e5c-735a0bcb2843' User entered 'None (0)'	System	07 Sep 2020 11:21:22
	System	07 Sep 2020 11:21:22

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:21:02', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fa1558f6-1a45-43d6-9e5c-735a0bcb2843' User entered 'None (0)'	System	07 Sep 2020 11:21:22
	System	07 Sep 2020 11:21:22

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:21:05', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fa1558f6-1a45-43d6-9e5c-735a0bcb2843' User entered 'None (0)'	System	07 Sep 2020 11:21:22
	System	07 Sep 2020 11:21:22

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:21:13', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fa1558f6-1a45-43d6-9e5c-735a0bcb2843' User entered 'No (N)'	System	07 Sep 2020 11:21:22
	System	07 Sep 2020 11:21:22

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-07T06:21:18', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fa1558f6-1a45-43d6-9e5c-735a0bcb2843' User entered '07 Sep 2020 06:21'	System	07 Sep 2020 11:21:22
	System	07 Sep 2020 11:21:22

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 4'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:17:27', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '634e3ad6-9218-4fbe-938b-6a2c7df8362a' User entered 'None (0)'	System	08 Sep 2020 14:18:06
	System	08 Sep 2020 14:18:06

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:17:31', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '634e3ad6-9218-4fbe-938b-6a2c7df8362a' User entered 'None (0)'	System	08 Sep 2020 14:18:06
	System	08 Sep 2020 14:18:06

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:17:36', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '634e3ad6-9218-4fbe-938b-6a2c7df8362a' User entered 'None (0)'	System	08 Sep 2020 14:18:06
	System	08 Sep 2020 14:18:06

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:17:41', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '634e3ad6-9218-4fbe-938b-6a2c7df8362a' User entered 'None (0)'	System	08 Sep 2020 14:18:06
	System	08 Sep 2020 14:18:06

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:42**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:17:46', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '634e3ad6-9218-4fbe-938b-6a2c7df8362a' User entered 'None (0)'	System	08 Sep 2020 14:18:06
	System	08 Sep 2020 14:18:06

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:17:49', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '634e3ad6-9218-4fbe-938b-6a2c7df8362a' User entered 'None (0)'	System	08 Sep 2020 14:18:06
	System	08 Sep 2020 14:18:06

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:17:57', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '634e3ad6-9218-4fbe-938b-6a2c7df8362a' User entered 'No (N)'	System	08 Sep 2020 14:18:06
	System	08 Sep 2020 14:18:06

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T09:18:01', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '634e3ad6-9218-4fbe-938b-6a2c7df8362a' User entered '08 Sep 2020 09:18'	System	08 Sep 2020 14:18:06
	System	08 Sep 2020 14:18:06

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 5'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:31:18', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '552f697c-05bb-4f8b-97ba-8381671a9d7d' User entered 'None (0)'	System	09 Sep 2020 01:32:04
	System	09 Sep 2020 01:32:04

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:31:23', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '552f697c-05bb-4f8b-97ba-8381671a9d7d' User entered 'None (0)'	System	09 Sep 2020 01:32:04
	System	09 Sep 2020 01:32:04

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:31:29', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '552f697c-05bb-4f8b-97ba-8381671a9d7d' User entered 'None (0)'	System	09 Sep 2020 01:32:04
	System	09 Sep 2020 01:32:04

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:31:34', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '552f697c-05bb-4f8b-97ba-8381671a9d7d' User entered 'None (0)'	System	09 Sep 2020 01:32:04
	System	09 Sep 2020 01:32:04

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:31:38', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '552f697c-05bb-4f8b-97ba-8381671a9d7d' User entered 'None (0)'	System	09 Sep 2020 01:32:04
	System	09 Sep 2020 01:32:04

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:31:42', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '552f697c-05bb-4f8b-97ba-8381671a9d7d' User entered 'None (0)'	System	09 Sep 2020 01:32:04
	System	09 Sep 2020 01:32:04

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:31:54', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '552f697c-05bb-4f8b-97ba-8381671a9d7d' User entered 'No (N)'	System	09 Sep 2020 01:32:04
	System	09 Sep 2020 01:32:04

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-08T20:31:58', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '552f697c-05bb-4f8b-97ba-8381671a9d7d' User entered '08 Sep 2020 20:31'	System	09 Sep 2020 01:32:04
	System	09 Sep 2020 01:32:04

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 6'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:43:01', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4bd034fc-6fca-4113-add1-da758c32f7c9' User entered 'None (0)'	System	10 Sep 2020 10:43:33
	System	10 Sep 2020 10:43:33

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:43:05', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4bd034fc-6fca-4113-add1-da758c32f7c9' User entered 'None (0)'	System	10 Sep 2020 10:43:33
	System	10 Sep 2020 10:43:33

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:43:08', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4bd034fc-6fca-4113-add1-da758c32f7c9' User entered 'None (0)'	System	10 Sep 2020 10:43:33
	System	10 Sep 2020 10:43:33

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:43:12', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4bd034fc-6fca-4113-add1-da758c32f7c9' User entered 'None (0)'	System	10 Sep 2020 10:43:33
	System	10 Sep 2020 10:43:33

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:43:15', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4bd034fc-6fca-4113-add1-da758c32f7c9' User entered 'None (0)'	System	10 Sep 2020 10:43:33
	System	10 Sep 2020 10:43:33

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:43:18', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4bd034fc-6fca-4113-add1-da758c32f7c9' User entered 'None (0)'	System	10 Sep 2020 10:43:33
	System	10 Sep 2020 10:43:33

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:43:24', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4bd034fc-6fca-4113-add1-da758c32f7c9' User entered 'No (N)'	System	10 Sep 2020 10:43:33
	System	10 Sep 2020 10:43:33

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T05:43:28', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '4bd034fc-6fca-4113-add1-da758c32f7c9' User entered '10 Sep 2020 05:43'	System	10 Sep 2020 10:43:33
	System	10 Sep 2020 10:43:33

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	04 Sep 2020 22:24:38
User entered 'Day 7'	System	04 Sep 2020 22:24:38

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:18:48', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '33454c6c-e68e-4033-9ef0-4614a7a1cc30' User entered 'None (0)'	System	10 Sep 2020 21:19:29
	System	10 Sep 2020 21:19:29

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:18:51', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '33454c6c-e68e-4033-9ef0-4614a7a1cc30' User entered 'None (0)'	System	10 Sep 2020 21:19:29
	System	10 Sep 2020 21:19:29

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:18:55', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '33454c6c-e68e-4033-9ef0-4614a7a1cc30' User entered 'None (0)'	System	10 Sep 2020 21:19:29
	System	10 Sep 2020 21:19:29

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:19:01', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '33454c6c-e68e-4033-9ef0-4614a7a1cc30' User entered 'None (0)'	System	10 Sep 2020 21:19:29
	System	10 Sep 2020 21:19:29

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:19:04', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '33454c6c-e68e-4033-9ef0-4614a7a1cc30' User entered 'None (0)'	System	10 Sep 2020 21:19:29
	System	10 Sep 2020 21:19:29

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:19:07', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '33454c6c-e68e-4033-9ef0-4614a7a1cc30' User entered 'None (0)'	System	10 Sep 2020 21:19:29
	System	10 Sep 2020 21:19:29

US3812062

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:19:16', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '33454c6c-e68e-4033-9ef0-4614a7a1cc30' User entered 'No (N)'	System	10 Sep 2020 21:19:29
	System	10 Sep 2020 21:19:29

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-09-10T16:19:23', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '33454c6c-e68e-4033-9ef0-4614a7a1cc30' User entered '10 Sep 2020 16:19'	System	10 Sep 2020 21:19:29
	System	10 Sep 2020 21:19:29

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:53:42**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 22:24:38

**US3812062**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	11 Sep 2020 21:27:07

**US3812062**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '11 Sep 2020'	Karen Knapp (b) (4)	11 Sep 2020 21:27:07

**US3812062**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	11 Sep 2020 21:27:07

**US3812062**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Karen Knapp (b) (4)	11 Sep 2020 21:27:07

US3812062

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	11 Sep 2020 21:27:12

**US3812062**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'I'	System	11 Sep 2020 21:27:12

**US3812062**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Sep 2020 19:51:34

**US3812062**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '18 Sep 2020'	Karen Knapp (b) (4)	18 Sep 2020 19:51:34

**US3812062**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	18 Sep 2020 19:51:34

US3812062

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Karen Knapp (b) (4)	18 Sep 2020 19:51:34

US3812062

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Sep 2020 19:51:38

**US3812062**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'I'	System	18 Sep 2020 19:51:38

**US3812062**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	27 Sep 2020 15:08:14

**US3812062**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '26 Sep 2020'	Karen Knapp (b) (4)	27 Sep 2020 15:08:14

US3812062

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:42

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	27 Sep 2020 15:08:14

**US3812062**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Karen Knapp (b) (4)	27 Sep 2020 15:08:14

US3812062

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	27 Sep 2020 15:08:17

**US3812062**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'I'	System	27 Sep 2020 15:08:17

**US3812062**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	12 Oct 2020 20:41:14

**US3812062**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:17:42
User entered '1 Oct 2020'	(b) (4)	
	Breanna Galibert (b) (4)	12 Oct 2020 20:41:14
	(b) (4)	

US3812062

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	12 Oct 2020 20:41:14

**US3812062**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'VISIT3'	System	12 Oct 2020 20:41:14

**US3812062**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	12 Oct 2020 20:41:38

US3812062

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:17:48
User entered '1 Oct 2020'	(b) (4)	
	Breanna Galibert (b) (4)	12 Oct 2020 20:41:38
	(b) (4)	

US3812062

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '15:22'	Breanna Galibert (b) (4)	12 Oct 2020 20:41:38

**US3812062**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered '01 Oct 2020 15:22'	System	11 Nov 2020 16:17:48
User entered '1 Oct 2020 15:22'	System	12 Oct 2020 20:41:38

US3812062

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '97.6' F	Breanna Galibert (b) (4)	12 Oct 2020 20:41:38

US3812062

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	12 Oct 2020 20:41:38

**US3812062**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	12 Oct 2020 20:41:38

**US3812062**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '76'	Breanna Galibert (b) (4)	12 Oct 2020 20:41:38

**US3812062**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'bpm'	System	12 Oct 2020 20:41:38

US3812062

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '14'	Breanna Galibert (b) (4)	12 Oct 2020 20:41:38

US3812062

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'breaths/min'	System	12 Oct 2020 20:41:38

US3812062

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '110'	Breanna Galibert (b) (4)	12 Oct 2020 20:41:38

**US3812062**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'mmHg'	System	12 Oct 2020 20:41:38

US3812062

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '68'	Breanna Galibert (b) (4)	12 Oct 2020 20:41:38

US3812062

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'mmHg'	System	12 Oct 2020 20:41:38

US3812062

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45

US3812062

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45

US3812062

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'No (N)'	Breanna Galibert (b) (4)	12 Oct 2020 20:41:47

US3812062

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Breanna Galibert (b) (4)	12 Oct 2020 20:41:47

US3812062

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	12 Oct 2020 20:41:58

US3812062

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 16:17:58
User entered '1 Oct 2020'	(b) (4)	
	Breanna Galibert (b) (4)	12 Oct 2020 20:41:58
	(b) (4)	

**US3812062**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:42**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '15:35'	Breanna Galibert (b) (4)	12 Oct 2020 20:41:58

**US3812062**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered '01 Oct 2020 15:35'	System	11 Nov 2020 16:17:58
User entered '1 Oct 2020 15:35'	System	12 Oct 2020 20:41:58

**US3812062**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Oct 2020 15:29:12

**US3812062**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'I'	System	18 Oct 2020 15:29:12

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 64'	System	06 Aug 2020 17:51:09

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-10-06T21:59:05', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '94d235d1-1efe-4480-af06-700a8ab3fa22'	System	07 Oct 2020 02:59:27
User entered 'No (N)'	System	07 Oct 2020 02:59:27

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

Have you been exposed to someone with 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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-10-06T21:59:16', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '94d235d1-1efe-4480-af06-700a8ab3fa22'	System	07 Oct 2020 02:59:27
User entered 'No (N)'	System	07 Oct 2020 02:59:27

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-10-06T21:59:25', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '94d235d1-1efe-4480-af06-700a8ab3fa22' User entered '06 Oct 2020 21:59:25'	System	07 Oct 2020 02:59:27
	System	07 Oct 2020 02:59:27

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 17:51:09

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 17:51:09

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 71'	System	06 Aug 2020 17:51:09

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

[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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-10-15T20:56:39', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '41ef41c8-1c8c-4136-8926-41d569da5493'	System	16 Oct 2020 01:57:34
User entered 'No (N)'	System	16 Oct 2020 01:57:34

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

Have you been exposed to someone with 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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-10-15T20:56:57', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '41ef41c8-1c8c-4136-8926-41d569da5493'	System	16 Oct 2020 01:57:34
User entered 'Yes (Y)'	System	16 Oct 2020 01:57:34

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Please 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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-10-15T20:57:12', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '41ef41c8-1c8c-4136-8926-41d569da5493'	System	16 Oct 2020 01:57:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Oct 2020 01:57:34

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-10-15T20:57:22', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '41ef41c8-1c8c-4136-8926-41d569da5493' User entered '15 Oct 2020 20:57:22'	System	16 Oct 2020 01:57:34
	System	16 Oct 2020 01:57:34

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 17:51:09

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 17:51:09

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 78'	System	06 Aug 2020 17:51:09

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

[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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-10-22T19:31:22', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '0513fd1b-6387-4a31-a924-0efe0891639d'	System	23 Oct 2020 00:31:44
User entered 'No (N)'	System	23 Oct 2020 00:31:44

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

Have you been exposed to someone with 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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-10-22T19:31:32', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '0513fd1b-6387-4a31-a924-0efe0891639d'	System	23 Oct 2020 00:31:44
User entered 'No (N)'	System	23 Oct 2020 00:31:44

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-10-22T19:31:41', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '0513fd1b-6387-4a31-a924-0efe0891639d' User entered '22 Oct 2020 19:31:41'	System	23 Oct 2020 00:31:44
	System	23 Oct 2020 00:31:44

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 17:51:09

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 17:51:09

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 92'	System	06 Aug 2020 17:51:09

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

[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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-05T23:39:12', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'ec89bc55-d453-41d9-90d5-7bb78d9af4c2'	System	06 Nov 2020 05:39:47
User entered 'No (N)'	System	06 Nov 2020 05:39:47

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

Have you been exposed to someone with 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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-05T23:39:35', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'ec89bc55-d453-41d9-90d5-7bb78d9af4c2'	System	06 Nov 2020 05:39:47
User entered 'No (N)'	System	06 Nov 2020 05:39:47

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-05T23:39:43', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'ec89bc55-d453-41d9-90d5-7bb78d9af4c2'	System	06 Nov 2020 05:39:47
User entered '05 Nov 2020 23:39:43'	System	06 Nov 2020 05:39:47

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 17:51:09

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 17:51:09

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 99'	System	06 Aug 2020 17:51:09

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

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)	06 Mar 2021 23:41:32
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 19:58:52
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'No MAE was performed. ' (Site from DM).	Angie Kean (b) (4) (b) (4)	05 Dec 2020 01:40:05
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 16:28:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-12T20:47:07', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'cc7dc8ee-2234-4c96-9838-c618b1e2909d'	System	13 Nov 2020 02:49:04
User entered 'Yes (Y)'	System	13 Nov 2020 02:49:04

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

Have you been exposed to someone with 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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-12T20:47:28', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'cc7dc8ee-2234-4c96-9838-c618b1e2909d' User entered 'No (N)'	System	13 Nov 2020 02:49:04
	System	13 Nov 2020 02:49:04

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

[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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-12T20:47:39', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'cc7dc8ee-2234-4c96-9838-c618b1e2909d' User entered 'No (N)'	System	13 Nov 2020 02:49:04
	System	13 Nov 2020 02:49:04

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

[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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-12T20:48:20', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'cc7dc8ee-2234-4c96-9838-c618b1e2909d' User entered 'Yes (Y)'	System	13 Nov 2020 02:49:04
	System	13 Nov 2020 02:49:04

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Please 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)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-12T20:48:45', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'cc7dc8ee-2234-4c96-9838-c618b1e2909d'	System	13 Nov 2020 02:49:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Nov 2020 02:49:04

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-12T20:48:54', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'cc7dc8ee-2234-4c96-9838-c618b1e2909d' User entered '12 Nov 2020 20:48:54'	System	13 Nov 2020 02:49:04
	System	13 Nov 2020 02:49:04

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 17:51:09

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:32
Data entry locked.	System	06 Aug 2020 17:51:09
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 17:51:09

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08
Data entry locked.	System	06 Aug 2020 17:51:09
User entered 'Day 106'	System	06 Aug 2020 17:51:09

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

US3812062

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:53:42

[Have you been exposed to someone with 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)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Please 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)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Please 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)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Please 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)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08
Data entry locked.	System	06 Aug 2020 17:51:09
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:49:08
Data entry locked.	System	06 Aug 2020 17:51:09
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 17:51:09

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-21T21:20:21', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd75dbcb3-6adf-492b-aec3-82bc157b1edf' User entered 'No (N)'	System	22 Nov 2020 03:20:39

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-21T21:20:29', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd75dbcb3-6adf-492b-aec3-82bc157b1edf' User entered 'No (N)'	System	22 Nov 2020 03:20:39

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-21T21:20:35', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'd75dbcb3-6adf-492b-aec3-82bc157b1edf' User entered '21 Nov 2020 21:20:35'	System	22 Nov 2020 03:20:39

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-28T12:29:37', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2fa34b93-11c3-4aa1-bffb-e76a1c5384ba' User entered 'No (N)'	System	28 Nov 2020 18:29:55
	System	28 Nov 2020 18:29:55

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-28T12:29:45', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2fa34b93-11c3-4aa1-bffb-e76a1c5384ba' User entered 'No (N)'	System	28 Nov 2020 18:29:55
	System	28 Nov 2020 18:29:55

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-11-28T12:29:52', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '2fa34b93-11c3-4aa1-bffb-e76a1c5384ba' User entered '28 Nov 2020 12:29:52'	System	28 Nov 2020 18:29:55
	System	28 Nov 2020 18:29:55

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-12-06T07:17:52', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'a4ac6486-ddb4-47e3-adf3-f55fc59467bd' User entered 'No (N)'	System	06 Dec 2020 13:18:13
	System	06 Dec 2020 13:18:13

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-12-06T07:18:01', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'a4ac6486-ddb4-47e3-adf3-f55fc59467bd' User entered 'No (N)'	System	06 Dec 2020 13:18:13
	System	06 Dec 2020 13:18:13

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-12-06T07:18:10', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'a4ac6486-ddb4-47e3-adf3-f55fc59467bd' User entered '06 Dec 2020 07:18:10'	System	06 Dec 2020 13:18:13
	System	06 Dec 2020 13:18:13

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-12-12T12:40:33', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'dbb38de1-395d-4e1a-9f55-24dd598901fc' User entered 'No (N)'	System	12 Dec 2020 18:40:56
	System	12 Dec 2020 18:40:56

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-12-12T12:40:44', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'dbb38de1-395d-4e1a-9f55-24dd598901fc' User entered 'No (N)'	System	12 Dec 2020 18:40:56
	System	12 Dec 2020 18:40:56

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-12-12T12:40:53', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'dbb38de1-395d-4e1a-9f55-24dd598901fc' User entered '12 Dec 2020 12:40:53'	System	12 Dec 2020 18:40:56
	System	12 Dec 2020 18:40:56

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-12-19T15:25:19', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '5eef7fb9-fc0e-4341-85ad-589d50e8b127'	System	19 Dec 2020 21:25:27
User entered 'No (N)'	System	19 Dec 2020 21:25:27

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-12-19T15:25:06', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '5eef7fb9-fc0e-4341-85ad-589d50e8b127'	System	19 Dec 2020 21:25:27
User entered 'No (N)'	System	19 Dec 2020 21:25:27

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-12-19T15:25:25', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '5eef7fb9-fc0e-4341-85ad-589d50e8b127' User entered '19 Dec 2020 15:25:25'	System	19 Dec 2020 21:25:27
	System	19 Dec 2020 21:25:27

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-12-27T11:36:45', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'ff47420d-347c-43de-942d-fbb8d1531b1c' User entered 'No (N)'	System	27 Dec 2020 17:36:59
	System	27 Dec 2020 17:36:59

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-12-27T11:36:51', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'ff47420d-347c-43de-942d-fbb8d1531b1c' User entered 'No (N)'	System	27 Dec 2020 17:36:59
	System	27 Dec 2020 17:36:59

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2020-12-27T11:36:57', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'ff47420d-347c-43de-942d-fbb8d1531b1c' User entered '27 Dec 2020 11:36:57'	System	27 Dec 2020 17:36:59
	System	27 Dec 2020 17:36:59

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-01-03T22:42:56', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'ac31563e-88c3-4b2b-b768-112e3e80f63c' User entered 'No (N)'	System	04 Jan 2021 04:43:09

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-01-03T22:43:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'ac31563e-88c3-4b2b-b768-112e3e80f63c'	System	04 Jan 2021 04:43:09
User entered 'No (N)'	System	04 Jan 2021 04:43:09

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-01-03T22:43:07', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'ac31563e-88c3-4b2b-b768-112e3e80f63c' User entered '03 Jan 2021 22:43:07'	System	04 Jan 2021 04:43:09
	System	04 Jan 2021 04:43:09

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-01-10T17:51:56', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '5c6d2ea8-ce75-4203-ae57-3f5738fd6f2a' User entered 'No (N)'	System	10 Jan 2021 23:52:11

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-01-10T17:52:02', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '5c6d2ea8-ce75-4203-ae57-3f5738fd6f2a' User entered 'No (N)'	System	10 Jan 2021 23:52:11

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-01-10T17:52:08', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '5c6d2ea8-ce75-4203-ae57-3f5738fd6f2a' User entered '10 Jan 2021 17:52:08'	System	10 Jan 2021 23:52:11
	System	10 Jan 2021 23:52:11

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-02-07T07:52:57', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '5f107175-21fc-43f1-8612-c17535b7c450'	System	07 Feb 2021 13:53:18
User entered 'No (N)'	System	07 Feb 2021 13:53:18

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-02-07T07:53:10', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '5f107175-21fc-43f1-8612-c17535b7c450'	System	07 Feb 2021 13:53:18
User entered 'No (N)'	System	07 Feb 2021 13:53:18

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-02-07T07:53:17', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '5f107175-21fc-43f1-8612-c17535b7c450'	System	07 Feb 2021 13:53:18
User entered '07 Feb 2021 07:53:17'	System	07 Feb 2021 13:53:18

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-02-15T15:32:15', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fb09d127-ce07-4ab0-80c6-164f755a3986'	System	15 Feb 2021 21:32:28
User entered 'No (N)'	System	15 Feb 2021 21:32:28

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-02-15T15:31:56', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fb09d127-ce07-4ab0-80c6-164f755a3986'	System	15 Feb 2021 21:32:28
User entered 'No (N)'	System	15 Feb 2021 21:32:28

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-02-15T15:32:24', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'fb09d127-ce07-4ab0-80c6-164f755a3986' User entered '15 Feb 2021 15:32:24'	System	15 Feb 2021 21:32:28
	System	15 Feb 2021 21:32:28

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-02-23T18:17:35-06:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '5736ef17-f9b3-4ba3-9ce4-bacd614b8657' User entered 'No (N)'	System	24 Feb 2021 00:18:09
	System	24 Feb 2021 00:18:09

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-02-23T18:17:39-06:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '5736ef17-f9b3-4ba3-9ce4-bacd614b8657' User entered 'No (N)'	System	24 Feb 2021 00:18:09
	System	24 Feb 2021 00:18:09

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-02-23T18:17:48-06:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '5736ef17-f9b3-4ba3-9ce4-bacd614b8657' User entered '24 Feb 2021 00:17:48'	System	24 Feb 2021 00:18:09
	System	24 Feb 2021 00:18:09

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-01T08:37:40-06:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '56993268-36ec-451e-9db4-1e604ec73f52'	System	01 Mar 2021 14:38:06
User entered 'No (N)'	System	01 Mar 2021 14:38:06

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-01T08:37:48-06:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '56993268-36ec-451e-9db4-1e604ec73f52'	System	01 Mar 2021 14:38:06
User entered 'No (N)'	System	01 Mar 2021 14:38:06

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-01T08:37:57-06:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '56993268-36ec-451e-9db4-1e604ec73f52'	System	01 Mar 2021 14:38:06
User entered '01 Mar 2021 08:37:57'	System	01 Mar 2021 14:38:06

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-07T20:42:48-06:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'a89ef0bc-825b-4273-b6b9-87f1047c023d'	System	08 Mar 2021 02:43:44
User entered 'No (N)'	System	08 Mar 2021 02:43:44

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-07T20:43:05-06:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'a89ef0bc-825b-4273-b6b9-87f1047c023d' User entered 'No (N)'	System	08 Mar 2021 02:43:44
	System	08 Mar 2021 02:43:44

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-07T20:43:15-06:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'a89ef0bc-825b-4273-b6b9-87f1047c023d' User entered '07 Mar 2021 20:43:15'	System	08 Mar 2021 02:43:44
	System	08 Mar 2021 02:43:44

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-17T15:22:33-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '46070ef4-eb02-4c35-9928-c4d34d950a2a' User entered 'No (N)'	System	17 Mar 2021 20:22:48
	System	17 Mar 2021 20:22:48

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-17T15:22:38-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '46070ef4-eb02-4c35-9928-c4d34d950a2a'	System	17 Mar 2021 20:22:48
User entered 'No (N)'	System	17 Mar 2021 20:22:48

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-17T15:22:44-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '46070ef4-eb02-4c35-9928-c4d34d950a2a' User entered '17 Mar 2021 15:22:44'	System	17 Mar 2021 20:22:48
	System	17 Mar 2021 20:22:48

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-22T09:41:37-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'a4ce0464-9b2d-48ad-91e9-c194c7a4d0b6'	System	22 Mar 2021 14:41:56
User entered 'No (N)'	System	22 Mar 2021 14:41:56

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-22T09:41:46-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'a4ce0464-9b2d-48ad-91e9-c194c7a4d0b6'	System	22 Mar 2021 14:41:56
User entered 'No (N)'	System	22 Mar 2021 14:41:56

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-22T09:41:50-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'a4ce0464-9b2d-48ad-91e9-c194c7a4d0b6'	System	22 Mar 2021 14:41:56
User entered '22 Mar 2021 09:41:50'	System	22 Mar 2021 14:41:56

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-30T20:34:20-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'ef77d816-aaa4-4940-a1af-2c4532dc8876'	System	31 Mar 2021 01:34:37
User entered 'No (N)'	System	31 Mar 2021 01:34:37

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-30T20:34:27-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'ef77d816-aaa4-4940-a1af-2c4532dc8876'	System	31 Mar 2021 01:34:37
User entered 'No (N)'	System	31 Mar 2021 01:34:37

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-30T20:34:32-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'ef77d816-aaa4-4940-a1af-2c4532dc8876' User entered '30 Mar 2021 20:34:32'	System	31 Mar 2021 01:34:37
	System	31 Mar 2021 01:34:37

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-04-25T12:13:29-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'e65f8116-e7bc-45ae-9f79-397c43f46d58'	System	25 Apr 2021 17:13:41
User entered 'No (N)'	System	25 Apr 2021 17:13:41

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-04-25T12:13:34-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'e65f8116-e7bc-45ae-9f79-397c43f46d58'	System	25 Apr 2021 17:13:41
User entered 'No (N)'	System	25 Apr 2021 17:13:41

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-04-25T12:13:38-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: 'e65f8116-e7bc-45ae-9f79-397c43f46d58' User entered '25 Apr 2021 12:13:38'	System	25 Apr 2021 17:13:41
	System	25 Apr 2021 17:13:41

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-05-03T20:00:47-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '85880965-b011-40df-a346-52c849ec0db2'	System	04 May 2021 01:03:10
User entered 'No (N)'	System	04 May 2021 01:03:10

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Have you been exposed to someone with 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 (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-05-03T20:00:41-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '85880965-b011-40df-a346-52c849ec0db2'	System	04 May 2021 01:03:10
User entered 'No (N)'	System	04 May 2021 01:03:10

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-05-03T20:00:51-05:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '85880965-b011-40df-a346-52c849ec0db2'	System	04 May 2021 01:03:10
User entered '03 May 2021 20:00:51'	System	04 May 2021 01:03:10

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:49:08

**US3812062**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:53:42**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:49:08
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:49:08

US3812062

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:53:42**

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 19:27:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-01T08:38:37-06:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6e05dfb1-1ebe-4267-88b1-cea3a083aff9'	System	01 Mar 2021 14:38:49
User entered 'No (N)'	System	01 Mar 2021 14:38:49

**US3812062**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:27:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (260B8D28-D8B0-41E4-855B-372DBCECCDA1)', Time: '2021-03-01T08:38:46-06:00', User OID: 'PatientReportedOutcome (US3812062)', ODM File OID: '6e05dfb1-1ebe-4267-88b1-cea3a083aff9'	System	01 Mar 2021 14:38:49
User entered '01 Mar 2021 08:38:46'	System	01 Mar 2021 14:38:49

**US3812062**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	30 Oct 2020 17:02:19

**US3812062**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '30 Oct 2020'	Karen Knapp (b) (4)	30 Oct 2020 17:02:19

**US3812062**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	30 Oct 2020 17:02:19

**US3812062**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Karen Knapp (b) (4)	30 Oct 2020 17:02:19

US3812062

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	30 Oct 2020 17:02:23

**US3812062**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:24:45
User entered 'I'	System	30 Oct 2020 17:02:23

**US3812062**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:23:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	03 Dec 2020 19:38:01

**US3812062**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:23:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '3 Dec 2020'	Karen Knapp (b) (4)	03 Dec 2020 19:38:01

**US3812062**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:23:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	03 Dec 2020 19:38:01

**US3812062**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:23:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Karen Knapp (b) (4)	03 Dec 2020 19:38:01

**US3812062**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:23:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User entered 'Yes (Y)'	Karen Knapp (b) (4)	03 Dec 2020 19:38:06

**US3812062**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:23:53
User entered 'I'	System	03 Dec 2020 19:38:06

**US3812062**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:23:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	30 Dec 2020 22:14:16

**US3812062**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:23:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '30 Dec 2020'	Karen Knapp (b) (4)	30 Dec 2020 22:14:16

**US3812062**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:23:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	30 Dec 2020 22:14:16

**US3812062**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:23:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Karen Knapp (b) (4)	30 Dec 2020 22:14:16

**US3812062**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:23:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	30 Dec 2020 22:14:22

**US3812062**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:23:53
User entered 'I'	System	30 Dec 2020 22:14:22

**US3812062**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:11:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	31 Jan 2021 17:55:14

US3812062

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:42

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:11:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered '31 Jan 2021'	Karen Knapp (b) (4)	31 Jan 2021 17:55:14

**US3812062**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:11:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	31 Jan 2021 17:55:14

US3812062

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:11:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered empty.	Karen Knapp (b) (4)	31 Jan 2021 17:55:14

US3812062

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:11:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:51
User entered 'Yes (Y)'	Karen Knapp (b) (4)	31 Jan 2021 17:55:18

**US3812062**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:11:07
User entered 'I'	System	31 Jan 2021 17:55:18

**US3812062**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 22:05:20

**US3812062**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 22:05:20

**US3812062**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	04 Mar 2021 22:05:20

**US3812062**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'VISIT4'	System	04 Mar 2021 22:05:20

US3812062

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	30 Mar 2021 16:16:36
User entered 'Yes (Y)'	Lyly Dang (b) (4)	30 Mar 2021 16:16:28

US3812062

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	30 Mar 2021 16:16:36
User entered '03 Mar 2021'	Lyly Dang (b) (4)	30 Mar 2021 16:16:28

**US3812062**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	30 Mar 2021 16:16:36
User entered '15:20'	Lyly Dang (b) (4)	30 Mar 2021 16:16:28

**US3812062**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '03 Mar 2021 15:20'	System	30 Mar 2021 16:16:28

US3812062

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	30 Mar 2021 16:16:36
User entered '98.1' F	Lyly Dang (b) (4)	30 Mar 2021 16:16:28

US3812062

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	30 Mar 2021 16:16:36
User entered 'Oral (Oral)'	Lyly Dang (b) (4)	30 Mar 2021 16:16:28

**US3812062**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	30 Mar 2021 16:16:36
User entered empty.	Lyly Dang (b) (4)	30 Mar 2021 16:16:28

**US3812062**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	30 Mar 2021 16:16:36
User entered '68'	Lyly Dang (b) (4)	30 Mar 2021 16:16:28

**US3812062**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:53:42**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'bpm'	System	30 Mar 2021 16:16:28

US3812062

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	30 Mar 2021 16:16:36
User entered '16'	Lyly Dang (b) (4)	30 Mar 2021 16:16:28

US3812062

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'breaths/min'	System	30 Mar 2021 16:16:28

US3812062

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	30 Mar 2021 16:16:36
User entered '148'	Lyly Dang (b) (4)	30 Mar 2021 16:16:28

US3812062

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'mmHg'	System	30 Mar 2021 16:16:28

US3812062

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	30 Mar 2021 16:16:36
User entered '82'	Lyly Dang (b) (4)	30 Mar 2021 16:16:28

US3812062

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'mmHg'	System	30 Mar 2021 16:16:28

US3812062

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 09:01:07

US3812062

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:53:42

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 09:01:07

US3812062

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:42

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 22:05:28

US3812062

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:53:42

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 22:05:28

US3812062

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 22:05:34

US3812062

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:42

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 22:05:34

**US3812062**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:42**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '15:05'	Breanna Galibert (b) (4)	04 Mar 2021 22:05:34

**US3812062**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered '03 Mar 2021 15:05'	System	04 Mar 2021 22:05:34

US3812062

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 22:05:38

**US3812062**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:07
User entered 'I'	System	04 Mar 2021 22:05:38

**US3812062**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
User entered 'Yes (Y)'	Maureen Dempsey (b) (4)	01 Apr 2021 14:20:48

**US3812062**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
User entered '1 Apr 2021'	Maureen Dempsey (b) (4)	01 Apr 2021 14:20:48

**US3812062**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:53:42**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
User entered 'Contact Made (CONTACT MADE)'	Maureen Dempsey (b) (4)	01 Apr 2021 14:20:48

US3812062

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:53:42

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
User entered empty.	Maureen Dempsey (b) (4)	01 Apr 2021 14:20:48

US3812062

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:53:42

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
User entered 'Yes (Y)'	Maureen Dempsey (b) (4)	01 Apr 2021 14:20:54

**US3812062**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:02
User entered 'I'	System	01 Apr 2021 14:20:54

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 22:05:49

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 22:05:49

US3812062

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:53:42

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 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). User entered 'Clinic (Clinic)' reason for change: Data Entry Error	System	04 Mar 2021 22:05:52
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System). User entered empty.	Breanna Galibert (b) (4)	04 Mar 2021 22:05:52
	(b) (4)	
	System	04 Mar 2021 22:05:49
	Breanna Galibert (b) (4)	04 Mar 2021 22:05:49
	(b) (4)	

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:53:42**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User entered 'UNBLND_DECIDE'	System	04 Mar 2021 22:05:49

US3812062

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:42

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 22:06:08

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:53:42**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '0'	Breanna Galibert (b) (4)	09 Mar 2021 16:07:51
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:21:52

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:53:42**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 22:06:08

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:53:42**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Amendment 6 or later (Amendment 6 or later)'	Breanna Galibert (b) (4)	09 Mar 2021 16:07:51
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:21:52

US3812062

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:42

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 22:06:08

US3812062

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:53:42

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'mRNA-1273 (mRNA-1273)'	Breanna Galibert (b) (4)	04 Mar 2021 22:06:08

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:53:42**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'mRNA-1273 (mRNA-1273)'	Breanna Galibert (b) (4)	04 Mar 2021 22:06:08

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:53:42**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'mRNA-1273 (mRNA-1273)'	Breanna Galibert (b) (4)	04 Mar 2021 22:06:08

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:53:42**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'No (N)'	Breanna Galibert (b) (4)	04 Mar 2021 22:06:08

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:53:42**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User entered empty.	System	04 Mar 2021 22:06:08

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:53:42**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User entered empty.	System	04 Mar 2021 22:06:08

US3812062

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 22:06:13

US3812062

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:53:42

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 22:06:13

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:42**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '15:05'	Breanna Galibert (b) (4)	04 Mar 2021 22:06:13

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:53:42**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User entered '03 Mar 2021 15:05'	System	04 Mar 2021 22:06:13

US3812062

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:53:42

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 22:06:18

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:53:42**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 22:06:18

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:53:42**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '15:10'	Breanna Galibert (b) (4)	04 Mar 2021 22:06:18

**US3812062**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:53:42**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:33
User entered '03 Mar 2021 15:10'	System	04 Mar 2021 22:06:18

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:53:42**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:01:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User entered 'Yes (Y)' reason for change: New Information	Breanna Galibert (b) (4)	19 Jan 2021 21:41:18
User entered 'No (N)'	Karen Knapp (b) (4)	03 Sep 2020 12:39:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:42

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:22
User entered	System	20 Jan 2021 12:41:19
'USA-US111-2021-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	20 Jan 2021 12:41:19

US3812062

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:42

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
	(b) (4), (b) (6)	20 Apr 2021 15:32:00
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:22:59
User closed query 'PV Query: Thank you for updating the event term to Hyponatremia. As the subject has a history of Hyponatremia, please consider updating the event term to worsening hyponatremia. ' (Site from Safety).		
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia aggravated - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 10:37:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 10:37:35
Query 'PV Query: Thank you for updating the event term to Hyponatremia. As the subject has a history of Hyponatremia, please consider updating the event term to worsening hyponatremia. ' answered with 'updated per PI' (Site from Safety).	Anya Penly (b) (4)	06 Apr 2021 21:02:09
Data point term sent to Coder	System	06 Apr 2021 21:02:06
Coding entries removed.	Anya Penly (b) (4)	06 Apr 2021 21:01:55
User entered 'WORSENING HYPONATREMIA' reason for change: New Information	Anya Penly (b) (4)	06 Apr 2021 21:01:55
User opened query 'PV Query: Thank you for updating the event term to Hyponatremia. As the subject has a history of Hyponatremia, please consider updating the event term to worsening hyponatremia. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:23:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 19:25:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Mar 2021 19:25:41
Data point term sent to Coder	System	23 Mar 2021 19:25:36
Coding entries removed.	Breanna Galibert (b) (4)	23 Mar 2021 19:25:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:42

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'hyponatremia' reason for change: New Breanna Galibert Information	(b) (4)	23 Mar 2021 19:25:05
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Malaise, LLT: Malaise - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 21:43:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 21:43:10
Data point term sent to Coder	System	19 Jan 2021 21:42:51
User entered 'malaise'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered 'No (N)'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered 'No (N)'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
	(b) (4), (b) (6)	20 Apr 2021 15:32:00
DataPoint Verified.	Breanna Galibert (b) (4)	23 Mar 2021 19:25:05
User entered '16 Jan 2021' reason for change: New Information	(b) (4)	
User entered '18 Jan 2021'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered empty.	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Jan 2021 21:42:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	24 Mar 2021 19:17:21
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Mar 2021 19:17:21
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	24 Mar 2021 19:17:21
User entered '20 Jan 2021' reason for change: Data Entry Error	Lyly Dang (b) (4)	24 Mar 2021 19:17:21
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Mar 2021 19:16:49
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)	11 Feb 2021 16:28:55
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 'BE ADVISED: "ONGOING" IS CHECKED BECAUSE IT IS STILL "ONGOING." HOW IS THERE AN END DATE IF IT IS ONGOING? ONGOING MEANS TO CONTINUE AND NOT END.' (Site from Safety).	Heather Cherniawski (b) (4)	10 Feb 2021 18:40:36
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)	28 Jan 2021 20:38:55
User entered empty.	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered empty.	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Jan 2021 21:42:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered 'Grade 4 (Grade 4)'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered '0'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered '0'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:42

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Feb 2021 17:58:54
User closed query 'Per CDM: Site response noted; however, please update the "Hospital Discharge Date" and "Admitted to ICU?" fields once available and then route back to DM. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 17:58:40
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'MEDICAL RECORDS HAVE NOT YET BEEN RECEIVED' (Site from System).	Heather Cherniawski (b) (4)	10 Feb 2021 18:51:33
Query 'Per CDM: Site response noted; however, please update the "Hospital Discharge Date" and "Admitted to ICU?" fields once available and then route back to DM. Thank you.' answered with 'UPDATAED' (Site from DM).	Heather Cherniawski (b) (4)	10 Feb 2021 18:51:08
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	10 Feb 2021 18:50:56
User opened query 'Per CDM: Site response noted; however, please update the "Hospital Discharge Date" and "Admitted to ICU?" fields once available and then route back to DM. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 12:23:47
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 17:28:41

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).	Lyly Dang (b) (4)	19 Jan 2021 21:49:36
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	19 Jan 2021 21:42:48
User entered '1'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48

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Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:42

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered '16 Jan 2021' reason for change: Data Entry Error	Lyly Dang (b) (4)	24 Mar 2021 19:13:46
User entered '18 Jan 2021' reason for change: Data Entry Error	Lyly Dang (b) (4)	19 Jan 2021 21:49:13
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	19 Jan 2021 21:43:42
	(b) (4)	
User entered '18 Jan 2021'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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Generated On: 10 Jun 2021 09:53:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:29:08
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'UPDATED' (Site from Safety).	Heather Cherniawski (b) (4)	10 Feb 2021 18:51:40
User entered '20 Jan 2021' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	10 Feb 2021 18:50:56
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:36:58
User entered empty.	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:42

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Lyly Dang (b) (4)	24 Mar 2021 19:13:46
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Jan 2021 21:43:42
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		19 Jan 2021 21:43:42
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	19 Jan 2021 21:43:42
	(b) (4)	
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Jan 2021 21:42:48
User entered 'Unknown (UNK)'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User closed query 'Admitted to ICU? is Yes, however System Number of Days in ICU is missing. Please review and reconcile.' (Site from System).		24 Mar 2021 19:16:35
Query 'Admitted to ICU? is Yes, however Number of System Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).		24 Mar 2021 19:16:35
User entered '3' reason for change: Data Entry Error	Lyly Dang (b) (4)	24 Mar 2021 19:16:35
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	24 Mar 2021 19:13:46
User entered empty.	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered '0'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered '0'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:42

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered '0'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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**Form: Adverse Events (1)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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**Folder: Adverse Events**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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Generated On: 10 Jun 2021 09:53:42

None

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered '0' reason for change: Data Entry Error	Heather Cherniawski	10 Feb 2021 18:50:56
	(b) (4)	
User entered '1'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
	(b) (4), (b) (6)	20 Apr 2021 15:32:00
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 14:11:37
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	Angie Kean (b) (4)	05 Mar 2021 21:19:42
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'med log line #19' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected for a hospitalized subject. Diagnostic procedures are not considered treatment Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:21:35
User entered '1' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	10 Feb 2021 18:50:56
User entered '0'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
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).	(b) (4), (b) (6)	12 Apr 2021 12:51:16
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 'all conprocedures entered pertain to this AE' (Site from DM).	Anya Penly (b) (4)	06 Apr 2021 21:02:58
	(b) (4)	
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).	(b) (4), (b) (6)	06 Apr 2021 11:27:48
User entered '1' reason for change: New Information	Breanna Galibert (b) (4)	25 Mar 2021 17:43:42
User entered '0'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:42

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:23:11
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'ok' (Site from Safety).	Lyly Dang (b) (4)	24 Mar 2021 19:18:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Lyly Dang (b) (4)	24 Mar 2021 19:16:49
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:39:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User entered empty.	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:42

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = ELEVATED TROPONIN LEVEL OF 17 NG/L, AND ELEVATED LFTS. 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)	26 Apr 2021 11:35:29
User closed query 'Per DM CLR: Narrative = PROLONGED QT INTERVAL. 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)	26 Apr 2021 11:34:12
User closed query 'Per DM CLR: Narrative = CHRONIC ISCHEMIC CHANGES, BRAIN ATROPHY. 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)	23 Apr 2021 05:25:37
User closed query 'Per DM CLR: Narrative = MEDICAL HISTORY OF DEPRESSION. 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)	23 Apr 2021 03:02:34
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:32:00
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:51:15
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'records have been submitted via email. ' (Site from Safety).	Angie Kean (b) (4) (b) (4)	16 Apr 2021 22:33:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:53:42

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = ZYPREXA 20 MG Q HS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 16:55:54
User closed query 'Per DM CLR: Narrative = ALTERED MENTAL STATUS AND FATIGUE. 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)	16 Apr 2021 13:37:40
Query 'Per DM CLR: Narrative = PROLONGED QT INTERVAL. 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 'AE added' (Site from DM).	Angie Kean (b) (4) (b) (4)	15 Apr 2021 19:13:10
Query 'Per DM CLR: Narrative = CHRONIC ISCHEMIC CHANGES, BRAIN ATROPHY. 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 'AE added' (Site from DM).	Angie Kean (b) (4) (b) (4)	15 Apr 2021 19:12:54
Query 'Per DM CLR: Narrative = ELEVATED TROPONIN LEVEL OF 17 NG/L, AND ELEVATED LFTS. 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 'AE added' (Site from DM).	Angie Kean (b) (4) (b) (4)	15 Apr 2021 19:12:34
Query 'Per DM CLR: Narrative = MEDICAL HISTORY OF DEPRESSION. 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 'done' (Site from DM).	Lyly Dang (b) (4)	14 Apr 2021 20:39:54

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = ZYPREXA 20 MG Q HS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'medical records were reconciled with subject on 23 Mar 2021; Subject denied taking 20 mg of zyprexa. Con med eCRF is correct' (Site from DM).	Lyly Dang (b) (4)	14 Apr 2021 20:15:56
Query 'Per DM CLR: Narrative = ALTERED MENTAL STATUS AND FATIGUE. 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 'Altered mental status and fatigue are signs and symptoms of hyponatremia; no AE indicated' (Site from DM).	Lyly Dang (b) (4)	14 Apr 2021 20:09:10
User closed query 'PV query: Please consider updating relevant medical history event brain aneurysm dipping to brain aneurysm clipping for consistency with event narrative case summary. ' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 18:23:09
Query 'PV query: Please consider updating relevant medical history event brain aneurysm dipping to brain aneurysm clipping for consistency with event narrative case summary. ' answered with 'updated MH' (Site from Safety).	Anya Penly (b) (4) (b) (4)	06 Apr 2021 21:04:04
User opened query 'Per DM CLR: Narrative = ZYPREXA 20 MG Q HS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:28:26
User opened query 'Per DM CLR: Narrative = PROLONGED QT INTERVAL. 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)	06 Apr 2021 11:28:20
User opened query 'Per DM CLR: Narrative = CHRONIC ISCHEMIC CHANGES, BRAIN ATROPHY. 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)	06 Apr 2021 11:28:15

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = ELEVATED TROPONIN LEVEL OF 17 NG/L, AND ELEVATED LFTS. 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)	06 Apr 2021 11:28:09
User opened query 'Per DM CLR: Narrative = MEDICAL HISTORY OF DEPRESSION. 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)	06 Apr 2021 11:28:01
User opened query 'Per DM CLR: Narrative = ALTERED MENTAL STATUS AND FATIGUE. 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)	06 Apr 2021 11:27:53
User opened query 'PV query: Please consider updating relevant medical history event brain aneurysm dipping to brain aneurysm clipping for consistency with event narrative case summary. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:22:57
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' canceled (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:22:32
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' canceled (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:22:24
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 13:23:15

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' answered with 'Hyponatremia was multifactorial. PI selected term for SAE is Hyponatremia. ' (Site from Safety).	Lyly Dang (b) (4)	24 Mar 2021 19:18:04
User entered 'Subject 3812062 is a 55-year-old female who presented to the ER on 16 Jan 2021 with a chief complaint of altered mental status and fatigue after falling earlier that week. Subject has medical history of depression, anxiety, bipolar disorder, and alcohol abuse. Other pertinent history includes HTN, cerebral aneurysm with clipping, hypokalemia, hyponatremia, and grand mal seizure. Labs obtained in the ER showed a sodium level of 106 mmol/L, potassium of 2.4 mmol/L, magnesium of 2.0 mg/dL, an elevated troponin level of 17 ng/L, and elevated LFTs. TSH and cortisol levels were normal. Labs also showed a serum osmolality of 217 mOsm/kg, urine osmolality of 249 mOsm/kg, and urine sodium of 47 mmol/L.	Lyly Dang (b) (4)	24 Mar 2021 19:12:58
Subject received 100 ml IV bolus of 3% sodium chloride, 2 grams of magnesium sulfate, and 20 mEq of potassium chloride while in the ER. Chest x-ray obtained in the ER was unremarkable. EKG showed prolonged QT interval. CT scan of the head showed chronic ischemic changes, brain atrophy, and aneurysm clipping without intracranial hemorrhage. Subject was transferred to the ICU for the following inpatient diagnoses: altered mental status, hyponatremia, hypokalemia, and prolonged QT interval. BMP was obtained q4hrs. Sodium chloride 0.9% infusion was given throughout the stay but specific dosage and times were not documented in medical record. Subject was discharged with the following medications: amlodipine 10 mg daily, nicotine patch daily, sodium chloride 1gram TID, thiamine 100 mg daily, and Zyprexa 20 mg q HS.' reason for change: Data Entry Error		
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:48:13

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:47:55
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' canceled (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:47:42
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 15:47:31
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 15:46:30
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:29:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:29:32
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)	11 Feb 2021 16:29:21
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:29:17
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'SUBJECT CONTINUES TO REPORT "JUST DIDN'T FEEL WELL". MALAISE AS AE TERM CONTINUES UNTIL MR RECIEVED TO DEEM OTHERWISE' (Site from Safety).	Heather Cherniawski (b) (4)	10 Feb 2021 18:54:01
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'STILL WAITING FOR MR' (Site from Safety).	Heather Cherniawski (b) (4)	10 Feb 2021 18:53:18
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 'STILL WAITING FOR MR' (Site from Safety).	Heather Cherniawski (b) (4)	10 Feb 2021 18:53:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'AT THIS TIME NO COVID TESTING FROM HOSPITAL IS KNOWN. STILL RETRIEVING MR' (Site from Safety).	Heather Cherniawski (b) (4)	10 Feb 2021 18:52:52
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:40:59
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:40:37
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)	28 Jan 2021 20:40:25
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:37:17
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 20:36:48
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Jan 2021 21:49:13

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	19 Jan 2021 21:49:13
User entered 'Subject 3812062 is a 55-year-old female with a past medical history of hypertension, dyslipidemia, bipolar disorder, anxiety, and chronic back pain who presented to the emergency department on 18 Jan 2021 with a chief complaint of malaise. Subject reported to site staff that she is currently in the hospital. The subject's admitting diagnosis is unknown at this time. Medical records will be requested and SAE will be updated once additional information is obtained.' reason for change: Data Entry Error	Lyly Dang (b) (4)	19 Jan 2021 21:49:13
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Jan 2021 21:42:48
User entered empty.	Breanna Galibert (b) (4)	19 Jan 2021 21:42:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 21:42:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Jan 2021 21:42:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 19:13:46
User entered '0'	System	19 Jan 2021 21:42:48

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:42

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPOKALEMIA. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 11:39:01
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPOKALEMIA. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'updated prior MH as it ended in 2019.' (Site from DM).	Anya Penly (b) (4)	06 Apr 2021 21:01:23
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPOKALEMIA. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:28:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 19:27:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 19:27:41
Data point term sent to Coder	System	23 Mar 2021 19:26:52
User entered 'hypokalemia'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	25 Mar 2021 14:18:36
User entered '16 Jan 2021' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Mar 2021 14:18:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Mar 2021 19:26:06
User entered 'un Jan 2021' (non-conformant).	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User entered empty.	System	23 Mar 2021 19:26:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '20 Jan 2021' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Mar 2021 14:18:36
User entered '21 Jan 2021'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User entered empty.	System	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

US3812062

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:42

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

US3812062

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:42

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

US3812062

Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

US3812062

Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

US3812062

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:42

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:53:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'I'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User entered '0'	System	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09
User entered 'I'	System	23 Mar 2021 19:26:06

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:09

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 19:27:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 19:27:42
Data point term sent to Coder	System	23 Mar 2021 19:26:52
User entered 'fall'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:42

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

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Folder: Adverse Events

Form: Adverse Events (3)

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Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '14 Jan 2021'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User entered empty.	System	23 Mar 2021 19:26:48

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '14 Jan 2021'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User entered empty.	System	23 Mar 2021 19:26:48

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:42

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

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**Folder: Adverse Events**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'I'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

US3812062

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:53:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User entered '0'	System	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15
User entered 'I'	System	23 Mar 2021 19:26:48

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:07:15

US3812062

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:42

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User coded data point as SOC: Investigations, HLT: Enzyme investigations NEC, HLT: Skeletal and cardiac muscle analyses, PT: Troponin increased, LLT: Troponin increased - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:16:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:16:03
Data point term sent to Coder	System	15 Apr 2021 19:15:30
User entered 'elevated troponin level'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Yes (Y)'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:42

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '16 Jan 2021'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:15:18

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Yes (Y)'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:15:18

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:42

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '1'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:53:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:15:18
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 19:15:18

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 19:15:18

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:42

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User coded data point as SOC: Investigations, HLT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Liver function test increased, LLT: Raised LFTs - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:17:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 19:17:36
Data point term sent to Coder	System	15 Apr 2021 19:16:31
User entered 'elevated LFT's'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Yes (Y)'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '16 Jan 2021'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:16:13

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Yes (Y)'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:16:13

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:53:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '1'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:16:13
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 19:16:13

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 19:16:13

US3812062

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:42

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User coded data point as SOC: Nervous system disorders, HLGT: Structural brain disorders, HLT: Structural brain disorders NEC, PT: Cerebral atrophy, LLT: Cerebral atrophy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 12:28:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 12:28:56
Data point term sent to Coder	System	15 Apr 2021 19:17:33
User entered 'chronic ischemic changes and atrophy of the brain'	Angie Kean (b) (4)	15 Apr 2021 19:17:32

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Yes (Y)'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '16 Jan 2021'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:17:32

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Yes (Y)'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:17:32

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:42

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '1'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:42

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:53:42

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:17:32
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 19:17:32

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 19:17:32

US3812062

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:53:42

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User coded data point as SOC: Investigations, HLT: Cardiac and vascular investigations (excl enzyme tests), HLT: ECG investigations, PT: Electrocardiogram QT prolonged, LLT: QT interval prolonged - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 08:37:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 08:37:31
Data point term sent to Coder	System	15 Apr 2021 19:18:34
User entered 'prolonged QT interval on EKG'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Yes (Y)'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '16 Jan 2021'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:18:27

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Yes (Y)'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 19:18:27

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'No (N)'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:53:42

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

US3812062

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:53:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '1'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered '0'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:11
User entered empty.	Angie Kean (b) (4)	15 Apr 2021 19:18:27
	(b) (4)	

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 19:18:27

**US3812062**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 19:18:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:53:42

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:01:02
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:53:51

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Aug 2020 23:28:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Aug 2020 23:28:23
Data point term sent to Coder	System	07 Aug 2020 16:54:40
User entered 'PROZAC'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:54:20

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:54:20
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'BIPOLAR'	Breanna Galibert (b) (4)	07 Aug 2020 16:54:20
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 14:22:42
	(b) (4)	
Signature has been broken.	Angie Kean (b) (4)	15 Apr 2021 19:26:06
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '30'	Breanna Galibert (b) (4)	07 Aug 2020 16:54:20
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	07 Aug 2020 16:54:20
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:54:20
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	07 Aug 2020 16:54:20
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:54:20
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	07 Aug 2020 16:54:20
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:54:20
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
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) (4), (b) (6)	11 Aug 2020 10:06:55
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 'DM ERROR' (Site from System).	Anya Penly (b) (4) (b) (4)	08 Aug 2020 17:21:33
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	07 Aug 2020 16:54:20
User entered 'UN Jul 2017'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:54:20

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:42

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:54:20
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:54:20
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:54:20
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:54:20
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 16:54:20

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 16:54:20

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 16:54:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: OLANZAPINE, PRODUCTSYNONYM: ZYPREXA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Aug 2020 16:57:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 16:57:14
Data point term sent to Coder	System	07 Aug 2020 16:56:44
User entered 'ZYPREXA'	Breanna Galibert (b) (4)	07 Aug 2020 16:55:48
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:55:48
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'BIPOLAR'	Breanna Galibert (b) (4)	07 Aug 2020 16:55:48
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '10'	Breanna Galibert (b) (4)	07 Aug 2020 16:55:48
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	07 Aug 2020 16:55:48
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:55:48
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'once daily (QD)' reason for change: Data Entry Error	Anya Penly (b) (4)	19 Nov 2020 22:50:47
	(b) (4)	
User entered 'other (OTHER)'	Breanna Galibert (b) (4)	07 Aug 2020 16:55:48
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User closed query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:48:31
Query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'updated to QD per DM request. ' (Site from DM).	Anya Penly (b) (4) (b) (4)	19 Nov 2020 22:51:29
User entered empty; reason for change Data Entry Error	Anya Penly (b) (4) (b) (4)	19 Nov 2020 22:50:47
User opened query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:42:37
User entered 'EVERY NIGHT'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:55:48

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	07 Aug 2020 16:55:48
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:55:48
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
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) (4), (b) (6)	11 Aug 2020 10:07:22
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 'DM ERROR' (Site from System).	Anya Penly (b) (4) (b) (4)	08 Aug 2020 17:21:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 16:55:48
User entered 'UN Jul 2017'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:55:48

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:42

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:55:48
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:55:48
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:55:48
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:55:48
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:50:47
User entered empty.	System	07 Aug 2020 16:55:48

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:50:47
User entered empty.	System	07 Aug 2020 16:55:48

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 22:50:47
User entered empty.	System	07 Aug 2020 16:55:48

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 16:57:14
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 16:57:14
	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 16:56:44
User entered 'HYDROXYZINE'	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'ANXIETY'	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '25'	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
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) (4), (b) (6)	11 Aug 2020 10:07:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'DM ERROR' (Site from System).	Anya Penly (b) (4) (b) (4)	08 Aug 2020 17:21:42
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).	System	07 Aug 2020 16:56:28
User entered 'UN Jul 2017'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:56:28

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:42

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:56:28
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 16:56:28

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 16:56:28

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 16:56:28

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Aug 2020 16:59:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 16:59:17
Data point term sent to Coder	System	07 Aug 2020 16:57:45
User entered 'IBUPROFEN'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:57:05

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:57:05
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'CHRONIC BACK PAIN'	Breanna Galibert (b) (4)	07 Aug 2020 16:57:05
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '800'	Breanna Galibert (b) (4)	07 Aug 2020 16:57:05
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	07 Aug 2020 16:57:05
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:57:05
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	07 Aug 2020 16:57:05
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:57:05
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	07 Aug 2020 16:57:05
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:57:05
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
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) (4), (b) (6)	11 Aug 2020 10:07:26
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 'DM ERROR' (Site from System).	Anya Penly (b) (4) (b) (4)	08 Aug 2020 17:21:46
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).	System	07 Aug 2020 16:57:05
User entered 'UN UNK 2013'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:57:05

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:57:05
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Anya Penly (b) (4)	28 Oct 2020 21:37:05
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:57:05
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '05 Aug 2020' reason for change: Data Entry Error	Anya Penly (b) (4)	28 Oct 2020 21:37:05
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:57:05
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:57:05
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 16:57:05

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 16:57:05

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 16:57:05

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
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.	(b) (4) Coder Import (b) (4) (b) (4)	07 Aug 2020 17:46:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 17:46:19
Data point term sent to Coder	System	07 Aug 2020 16:58:47
User entered 'ATROVASTATIN'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:58:07

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:07
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'HIGH CHOLESTEROL'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:07
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '10'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:07
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:07
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:58:07
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'once daily (QD)' reason for change: Data Entry Error	Anya Penly (b) (4)	19 Nov 2020 22:51:45
	(b) (4)	
User entered 'other (OTHER)'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:07
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User closed query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:48:40
Query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'updated per DM request' (Site from DM).	Anya Penly (b) (4) (b) (4)	19 Nov 2020 22:51:57
User entered empty; reason for change Data Entry Error	Anya Penly (b) (4) (b) (4)	19 Nov 2020 22:51:45
User opened query 'Per CDM: Per page 37 of CCGs, Select the frequency using the drop-down list provided. If the frequency is not available from the list of choices, select 'Other', and specify in the text box provided. However the frequency indicated in the other specify is one of the available option "once daily" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 14:42:47
User entered 'EVERY NIGHT'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:58:07

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:07
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:58:07
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
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) (4), (b) (6)	11 Aug 2020 10:07:28
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 'DM ERROR' (Site from System).	Anya Penly (b) (4) (b) (4)	08 Aug 2020 17:21:50
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	07 Aug 2020 16:58:07
User entered 'UN Feb 2020'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:58:07

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:07
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:07
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:58:07
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:07
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:51:45
User entered empty.	System	07 Aug 2020 16:58:07

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 22:51:45
User entered empty.	System	07 Aug 2020 16:58:07

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 22:51:45
User entered empty.	System	07 Aug 2020 16:58:07

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 13:40:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 13:40:09
Data point term sent to Coder	System	07 Aug 2020 16:59:48
User entered 'METHOCARBAMOL'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:58:53

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:53
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'CHRONIC BACK PAIN'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:53
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '750'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:53
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:53
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:58:53
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:53
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:58:53
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:53
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:58:53
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
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) (4), (b) (6)	11 Aug 2020 10:07:31
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'DM ERROR' (Site from System).	Anya Penly (b) (4) (b) (4)	08 Aug 2020 17:21:54
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).	System	07 Aug 2020 16:58:53
User entered 'UN UNK 2019'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:58:53

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:42

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:53
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:53
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:58:53
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:58:53
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 16:58:53

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 16:58:53

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 16:58:53

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Aug 2020 17:11:16
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 Aug 2020 17:11:16
Data point term sent to Coder	System	07 Aug 2020 16:59:50
User entered 'MELOXICAM'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:59:24

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:59:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'CHRONIC BACK PAIN'	Breanna Galibert (b) (4)	07 Aug 2020 16:59:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '15'	Breanna Galibert (b) (4)	07 Aug 2020 16:59:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	07 Aug 2020 16:59:24
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:42**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:59:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	07 Aug 2020 16:59:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:59:24
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	07 Aug 2020 16:59:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:59:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
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) (4), (b) (6)	11 Aug 2020 10:07:34
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 'DM ERROR' (Site from System).	Anya Penly (b) (4) (b) (4)	08 Aug 2020 17:21:58
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).	System	07 Aug 2020 16:59:24
User entered 'UN UNK 2019'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 16:59:24

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 16:59:24
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 16:59:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 16:59:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 16:59:24
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 16:59:24

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 16:59:24

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 16:59:24

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: ERGOCALCIFEROL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 00:14:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 00:14:11
Data point term sent to Coder	System	07 Aug 2020 17:00:51
User entered 'ERGOCALCIFEROL'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 17:00:17

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:42**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:17
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'VITAMIN D DEFICIENCY'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:17
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 14:22:42
	(b) (4)	
Signature has been broken.	Angie Kean (b) (4)	15 Apr 2021 19:29:02
	(b) (4)	
User entered '50,000' reason for change: New Information	Angie Kean (b) (4)	15 Apr 2021 19:29:02
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '1.25'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:17
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 14:22:42
	(b) (4)	
Signature has been broken.	Angie Kean (b) (4)	15 Apr 2021 19:29:02
	(b) (4)	
User entered 'IU (IU)' reason for change: New Information	Angie Kean (b) (4)	15 Apr 2021 19:29:02
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:17
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:42**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 17:00:17
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:48:47
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'DATA IS CORRECT PER SUBJECT/SORCE AND MEDICAL RECORDS. DIRECTIONS OF THE PRIMARY PHYSICIAN' (Site from DM).	Angie Kean (b) (4) (b) (4)	21 Oct 2020 13:05:50
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 02:37:28
User entered 'every week (QS)'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 17:00:17

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 17:00:17
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:17
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 17:00:17
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
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) (4), (b) (6)	11 Aug 2020 10:07:36
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 'DM ERROR' (Site from System).	Anya Penly (b) (4) (b) (4)	08 Aug 2020 17:22:02
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).	System	07 Aug 2020 17:00:17
User entered 'UN UNK 2019'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 17:00:17

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:17
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:17
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 17:00:17
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:17
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 17:00:17

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 17:00:17

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	07 Aug 2020 17:00:17

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Aug 2020 17:03:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 17:03:14
Data point term sent to Coder	System	07 Aug 2020 17:01:52
User entered 'METOPROLOL TARTRATE'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 17:00:59

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'HYPERTENSION'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '50'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 17:00:59
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:42**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'twice daily (BID)'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 17:00:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:59
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 17:00:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
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) (4), (b) (6)	11 Aug 2020 10:07:40
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 'DM ERROR' (Site from System).	Anya Penly (b) (4) (b) (4)	08 Aug 2020 17:22:05
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	07 Aug 2020 17:00:59
User entered 'UN Jul 2017'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 17:00:59

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Anya Penly (b) (4)	19 Nov 2020 22:57:41
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '12 Nov 2020' reason for change: Data Entry Error	Anya Penly (b) (4)	19 Nov 2020 22:57:41
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 17:00:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 17:00:59
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Aug 2020 17:00:59

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 17:00:59

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 17:00:59

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL, PRODUCTSYNONYM: LISINOPRIL/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Sep 2020 14:30:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:30:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 07:01:23
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 07:01:23
Data point term sent to Coder	System	07 Aug 2020 17:02:53
User entered 'LISINOPRIL-10 MG HYDROCHLOROTHIAZIDE-12.5 MG'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 17:02:40

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 17:02:40
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'HYPERTENSION'	Breanna Galibert (b) (4)	07 Aug 2020 17:02:40
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '1'	Breanna Galibert (b) (4)	07 Aug 2020 17:02:40
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Anya Penly (b) (4)	19 Nov 2020 22:48:28
	(b) (4)	
User entered 'Other (OTHER)'	Breanna Galibert (b) (4)	07 Aug 2020 17:02:40
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "tablet" or "capsule" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:48:53
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "tablet" or "capsule" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'corrected' (Site from DM).	Anya Penly (b) (4) (b) (4)	19 Nov 2020 22:48:35
User entered empty; reason for change Data Entry Error	Anya Penly (b) (4) (b) (4)	19 Nov 2020 22:48:28
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "tablet" or "capsule" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:51:09
User entered 'PILL'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 17:02:40

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	07 Aug 2020 17:02:40
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 17:02:40
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	07 Aug 2020 17:02:40
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 17:02:40
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
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) (4), (b) (6)	11 Aug 2020 10:07:42
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 'DM ERROR' (Site from System).	Anya Penly (b) (4) (b) (4)	08 Aug 2020 17:22:09
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	07 Aug 2020 17:02:40
User entered 'UN Jul 2017'	Breanna Galibert (b) (4) (b) (4)	07 Aug 2020 17:02:40

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 17:02:40
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Heather Cherniawski	10 Feb 2021 17:50:09
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 17:02:40
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '20 Jan 2021' reason for change: Data Entry Error	Heather Cherniawski	10 Feb 2021 17:50:09
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 17:02:40
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 17:02:40
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 17:02:40

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 17:02:40

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 17:02:40

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:42

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User closed query 'Per DM CLR: This Con Med was added on 07 AUG 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	(b) (4) (b) (4), (b) (6) Coder Import (b) (4) (b) (4)	19 Nov 2020 09:35:26 29 Oct 2020 21:08:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:08:57
Data point term sent to Coder	System	28 Oct 2020 21:42:22
Query 'Per DM CLR: This Con Med was added on 07 AUG 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'Not worsening or exacerbation. This is the subject's normal regimen. ' (Site from DM).	Anya Penly (b) (4) (b) (4)	28 Oct 2020 21:42:02
Coding entries removed.	Anya Penly (b) (4) (b) (4)	28 Oct 2020 21:41:32
Coding entries removed.	Anya Penly (b) (4) (b) (4)	28 Oct 2020 21:41:32
User entered 'MOTRIN [Ibuprofen]' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	28 Oct 2020 21:41:32
User opened query 'Per DM CLR: This Con Med was added on 07 AUG 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 02:39:46

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 23:38:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 23:38:19
Data point term sent to Coder	System	22 Aug 2020 23:37:07
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 23:36:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 23:36:18
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	22 Aug 2020 23:36:14
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:10:05
Data point term sent to Coder	System	13 Aug 2020 20:51:43
User entered 'MOTRIN'	Breanna Galibert (b) (4) (b) (4)	13 Aug 2020 20:50:45

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Chronic back pain' reason for change: Data Entry Error	Anya Penly (b) (4)	28 Oct 2020 21:41:32
	(b) (4)	
User entered 'DEGENERATIVE DISC DISEASE'	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '800'	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:42**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '07 Aug 2020'	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '08 Aug 2020'	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	13 Aug 2020 20:50:45
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:50:45

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:50:45

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 20:50:45

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Sep 2020 06:30:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Sep 2020 06:30:40
Data point term sent to Coder	System	18 Sep 2020 21:54:20
User entered 'PPV23 vaccine'	Any Penly (b) (4) (b) (4)	18 Sep 2020 21:53:56
DataPoint activated with code reason code Data required.	Any Penly (b) (4) (b) (4)	18 Sep 2020 21:52:53
DataPoint inactivated with code reason code Data not required.	Any Penly (b) (4) (b) (4)	25 Aug 2020 15:42:51

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Any Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Any Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Any Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Pneumonia prevention'	Any Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Any Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Any Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '1'	Any Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Any Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Any Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Other (OTHER)'	Anya Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Anya Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anya Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'dose'	Any Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Any Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Any Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'once (ONCE)'	Any Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Any Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Any Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Anya Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Anya Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Anya Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Any Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Any Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Any Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Any Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Any Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Any Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '10 Jul 2020'	Any Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Any Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Any Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Any Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Any Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Any Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Any Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Any Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Any Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '10 Jul 2020'	Any Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Any Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Any Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Any Penly (b) (4)	18 Sep 2020 21:53:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Any Penly (b) (4)	18 Sep 2020 21:52:53
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Any Penly (b) (4)	25 Aug 2020 15:42:51
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 21:53:56
DataPoint activated with code reason code Data required.	Anya Penly (b) (4)	18 Sep 2020 21:52:53
DataPoint inactivated with code reason code Data not required.	Anya Penly (b) (4)	25 Aug 2020 15:42:51

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 21:53:56
DataPoint activated with code reason code Data required.	Anya Penly (b) (4)	18 Sep 2020 21:52:53
DataPoint inactivated with code reason code Data not required.	Anya Penly (b) (4)	25 Aug 2020 15:42:51

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:53:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 21:53:56
DataPoint activated with code reason code Data required.	Anya Penly (b) (4)	18 Sep 2020 21:52:53
DataPoint inactivated with code reason code Data not required.	Anya Penly (b) (4)	25 Aug 2020 15:42:51

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	29 Oct 2020 21:08:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:08:57
Data point term sent to Coder	System	28 Oct 2020 21:43:23
User entered 'motrin [Ibuprofen]'	Anya Penly (b) (4) (b) (4)	28 Oct 2020 21:42:59

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Any Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:42**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'chronic back pain'	Any Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '800'	Any Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Any Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Anya Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'as needed (PRN)'	Any Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Any Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Any Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Any Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '25 Aug 2020'	Any Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Any Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Any Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '25 Aug 2020'	Any Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Any Penly (b) (4)	28 Oct 2020 21:42:59
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 21:42:59

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 21:42:59

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 21:42:59

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Nov 2020 22:50:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:50:49
Data point term sent to Coder	System	19 Nov 2020 22:49:53
User entered 'flu vaccine'	Any Penly (b) (4) (b) (4)	19 Nov 2020 22:49:33

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Any Penly (b) (4)	19 Nov 2020 22:49:33
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'influenza prevention'	Any Penly (b) (4)	19 Nov 2020 22:49:33
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '1'	Any Penly (b) (4)	19 Nov 2020 22:49:33
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Other (OTHER)'	Any Penly (b) (4)	19 Nov 2020 22:49:33
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'dose'	Any Penly (b) (4)	19 Nov 2020 22:49:33
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'once (ONCE)'	Any Penly (b) (4)	19 Nov 2020 22:49:33
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Any Penly (b) (4)	19 Nov 2020 22:49:33
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Any Penly (b) (4) (b) (4)	19 Nov 2020 22:49:33

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Any Penly (b) (4)	19 Nov 2020 22:49:33
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '16 Oct 2020'	Any Penly (b) (4)	19 Nov 2020 22:49:33
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Any Penly (b) (4)	19 Nov 2020 22:49:33
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Any Penly (b) (4)	19 Nov 2020 22:49:33
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '16 Oct 2020'	Any Penly (b) (4)	19 Nov 2020 22:49:33
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Any Penly (b) (4)	19 Nov 2020 22:49:33
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:49:33

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:49:33

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 22:49:33

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
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)	19 Nov 2020 23:03:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:03:49
Data point term sent to Coder	System	19 Nov 2020 23:03:11
User entered 'tylenol'	Any Penly (b) (4) (b) (4)	19 Nov 2020 23:02:13

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Any Penly (b) (4)	19 Nov 2020 23:02:13
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 08:56:34
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' answered with 'solicited event does not meet criteria for AE' (Site from DM).	Angie Kean (b) (4) (b) (4)	13 Jan 2021 21:18:04
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 07:34:14

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User entered 'pain at injection site'	Anya Penly (b) (4) (b) (4)	19 Nov 2020 23:02:13

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '500'	Any Penly (b) (4)	19 Nov 2020 23:02:13
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Any Penly (b) (4)	19 Nov 2020 23:02:13
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Any Penly (b) (4)	19 Nov 2020 23:02:13
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'once (ONCE)'	Any Penly (b) (4)	19 Nov 2020 23:02:13
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Any Penly (b) (4)	19 Nov 2020 23:02:13
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Any Penly (b) (4)	19 Nov 2020 23:02:13
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Any Penly (b) (4)	19 Nov 2020 23:02:13
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '4 Sep 2020'	Any Penly (b) (4)	19 Nov 2020 23:02:13
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Any Penly (b) (4)	19 Nov 2020 23:02:13
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Any Penly (b) (4)	19 Nov 2020 23:02:13
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '4 Sep 2020'	Any Penly (b) (4)	19 Nov 2020 23:02:13
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Any Penly (b) (4)	19 Nov 2020 23:02:13
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:02:13

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:02:13

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:02:13

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 12:06:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 12:06:43
Data point term sent to Coder	System	25 Mar 2021 15:16:36
Coding entries removed.	Lyly Dang (b) (4)	25 Mar 2021 15:16:19
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:35:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 00:35:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 00:35:47
Data point term sent to Coder	System	10 Feb 2021 18:59:14
User entered 'AMLODIPINE'	Heather Cherniawski (b) (4)	10 Feb 2021 18:59:06

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Feb 2021 18:59:06
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:47:38
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'all medications treated throughout hospitalization reflect standard of care to stabilize SAE term "hyponatremia". Please keep this medication under this SAE term - Lyly Dang, NP-C' (Site from DM).	Lyly Dang (b) (4)	25 Mar 2021 15:18:53
Signature has been broken.	Lyly Dang (b) (4)	25 Mar 2021 15:16:19
User entered 'Hyponatremia ' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Mar 2021 15:16:19
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:20:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User entered 'MALAISE'	Heather Cherniawski (b) (4)	10 Feb 2021 18:59:06

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '10'	Heather Cherniawski	10 Feb 2021 18:59:06
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Heather Cherniawski	10 Feb 2021 18:59:06
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 18:59:06
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'once daily (QD)'	Heather Cherniawski	10 Feb 2021 18:59:06
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 18:59:06
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:42**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Heather Cherniawski	10 Feb 2021 18:59:06
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 18:59:06
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '20 Jan 2021'	Heather Cherniawski	10 Feb 2021 18:59:06
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Heather Cherniawski	10 Feb 2021 18:59:06
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
Signature has been broken.	Breanna Galibert (b) (4)	04 Mar 2021 22:07:33
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	04 Mar 2021 22:07:33
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	10 Feb 2021 18:59:06
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
Signature has been broken.	Breanna Galibert (b) (4)	04 Mar 2021 22:07:33
	(b) (4)	
User entered '20 Feb 2021' reason for change: New Information	Breanna Galibert (b) (4)	04 Mar 2021 22:07:33
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 18:59:06
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 19:02:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 19:02:51
User entered 'No (N)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	10 Feb 2021 19:02:51
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 18:59:06
User entered empty.	Heather Cherniawski (b) (4)	10 Feb 2021 18:59:06

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User entered '1'	System	10 Feb 2021 18:59:06

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User entered '1'	System	10 Feb 2021 18:59:06

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:53:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:40
User entered '804 (804)'	System	10 Feb 2021 18:59:06

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: VITAMIN B1 NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 09:07:31
Data point term sent to Coder	System	25 Mar 2021 14:25:36
Coding entries removed.	Lyly Dang (b) (4) (b) (4) (b) (4)	25 Mar 2021 14:25:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: VITAMIN B1 NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Mar 2021 17:56:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Mar 2021 17:56:11
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:35:37
Data point term sent to Coder	System	10 Feb 2021 19:01:16
User entered 'VITAMIN B1'	Heather Cherniawski (b) (4)	10 Feb 2021 19:00:27

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Feb 2021 19:00:27
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
Signature has been broken.	Lyly Dang (b) (4)	25 Mar 2021 14:25:21
User entered 'Hyponatremia' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Mar 2021 14:25:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'MALAISE'	Heather Cherniawski	10 Feb 2021 19:00:27
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
Signature has been broken.	Lyly Dang (b) (4)	25 Mar 2021 14:25:21
User entered '100' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Mar 2021 14:25:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'UNK'	Heather Cherniawski	10 Feb 2021 19:00:27
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'capsule (CAPSULE)'	Heather Cherniawski	10 Feb 2021 19:00:27
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 19:00:27
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'once daily (QD)'	Heather Cherniawski	10 Feb 2021 19:00:27
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 19:00:27
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:42**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Heather Cherniawski	10 Feb 2021 19:00:27
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 19:00:27
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '20 Jan 2021'	Heather Cherniawski	10 Feb 2021 19:00:27
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Heather Cherniawski	10 Feb 2021 19:00:27
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	04 Mar 2021 22:06:55
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	04 Mar 2021 22:06:55
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	10 Feb 2021 19:00:27
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	04 Mar 2021 22:06:55
	(b) (4)	
User entered '20 Feb 2021' reason for change: New Information	Breanna Galibert (b) (4)	04 Mar 2021 22:06:55
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 19:00:27
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 19:03:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 19:03:02
User entered 'No (N)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	10 Feb 2021 19:03:02
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 19:00:27
User entered empty.	Heather Cherniawski (b) (4)	10 Feb 2021 19:00:27

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 19:00:27

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 19:00:27

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Feb 2021 19:00:27

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: SODIUM, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:48:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 11:48:17
Data point term sent to Coder	System	25 Mar 2021 15:20:46
Coding entries removed.	Lyly Dang (b) (4) (b) (4) (b) (4)	25 Mar 2021 15:20:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: SODIUM, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:18:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:18:42
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:35:37
Data point term sent to Coder	System	10 Feb 2021 19:02:17
User entered 'SODIUM CHLORIDE'	Heather Cherniawski (b) (4)	10 Feb 2021 19:01:21

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Feb 2021 19:01:21
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
Signature has been broken.	Lyly Dang (b) (4)	25 Mar 2021 15:20:15
User entered 'Hyponatremia' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Mar 2021 15:20:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'MALAISE'	Heather Cherniawski	10 Feb 2021 19:01:21
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '1'	Heather Cherniawski	10 Feb 2021 19:01:21
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'g (g)'	Heather Cherniawski	10 Feb 2021 19:01:21
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 19:01:21
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'three times daily (TID)'	Heather Cherniawski	10 Feb 2021 19:01:21
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 19:01:21
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Heather Cherniawski	10 Feb 2021 19:01:21
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 19:01:21
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '20 Jan 2021'	Heather Cherniawski	10 Feb 2021 19:01:21
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Heather Cherniawski	10 Feb 2021 19:01:21
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	04 Mar 2021 22:07:17
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	04 Mar 2021 22:07:17
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	10 Feb 2021 19:01:21
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	04 Mar 2021 22:07:17
	(b) (4)	
User entered '27 Jan 2021' reason for change: New Information	Breanna Galibert (b) (4)	04 Mar 2021 22:07:17
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 19:01:21
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 19:02:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 19:02:31
User entered 'No (N)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	10 Feb 2021 19:02:31
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 19:01:21
User entered empty.	Heather Cherniawski (b) (4)	10 Feb 2021 19:01:21

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Feb 2021 19:01:21

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 19:01:21

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Feb 2021 19:01:21

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:53:42

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 10:20:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 10:20:16
Data point term sent to Coder	System	25 Mar 2021 15:19:39
Coding entries removed.	Lyly Dang (b) (4) (b) (4) (b) (4)	25 Mar 2021 15:19:25
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 19:35:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 13:26:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 13:26:52
Data point term sent to Coder	System	10 Feb 2021 19:02:17
User entered 'METOPROLOL'	Heather Cherniawski (b) (4)	10 Feb 2021 19:02:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Feb 2021 19:02:15
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 08:45:11
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'all medications treated throughout hospitalization reflect standard of care to stabilize SAE term "hyponatremia". Please keep this medication under this SAE term' (Site from DM). Signature has been broken.	Lyly Dang (b) (4)	25 Mar 2021 15:19:29
User entered 'Hyponatremia' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Mar 2021 15:19:25
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:20:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User entered 'MALAISE'	Heather Cherniawski (b) (4)	10 Feb 2021 19:02:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '50'	Heather Cherniawski	10 Feb 2021 19:02:15
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'mg (mg)'	Heather Cherniawski	10 Feb 2021 19:02:15
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:42**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 19:02:15
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'twice daily (BID)'	Heather Cherniawski	10 Feb 2021 19:02:15
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:42**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 19:02:15
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Oral (ORAL)'	Heather Cherniawski	10 Feb 2021 19:02:15
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:42**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 19:02:15
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '20 Jan 2021'	Heather Cherniawski	10 Feb 2021 19:02:15
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:53:42

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '0'	Heather Cherniawski	10 Feb 2021 19:02:15
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	10 Feb 2021 19:02:15
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered empty.	Heather Cherniawski	10 Feb 2021 19:02:15
	(b) (4)	

US3812062

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:42**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	10 Feb 2021 19:02:15
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Feb 2021 19:02:15

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 19:02:15

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Feb 2021 19:02:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:07:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:07:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:46:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:46:41
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
Data point term sent to Coder	System	23 Mar 2021 19:42:13
User entered 'magnesium sulfate'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 19:41:24

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'HYPONATREMIA'	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:42**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered '2/50'	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'Other (OTHER)'	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'g/ml'	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User closed query 'Per DM CLR: Please review the Frequency = ONCE DAILY. However, the medication timeframe is only 1 day, please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 11:36:21
User signature succeeded.	Lyly Dang (b) (4)	16 Apr 2021 14:22:42
Query 'Per DM CLR: Please review the Frequency = ONCE DAILY. However, the medication timeframe is only 1 day, please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Angie Kean (b) (4)	15 Apr 2021 19:20:47
Signature has been broken.	Angie Kean (b) (4)	15 Apr 2021 19:20:18
User entered 'once (ONCE)' reason for change: Data Entry Error	Angie Kean (b) (4)	15 Apr 2021 19:20:18
User opened query 'Per DM CLR: Please review the Frequency = ONCE DAILY. However, the medication timeframe is only 1 day, please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:53:45
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'Intravenous (INTRAVENOUS)'	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered '16 Jan 2021'	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered '16 Jan 2021'	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:41:24
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User entered empty.	System	15 Apr 2021 19:20:18
User entered '1'	System	23 Mar 2021 19:41:24

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User entered empty.	System	15 Apr 2021 19:20:18
User entered 'I'	System	23 Mar 2021 19:41:24

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:53:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:46
User entered empty.	System	15 Apr 2021 19:20:18
User entered '804 (804)'	System	23 Mar 2021 19:41:24

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 09:12:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 09:12:39
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 14:24:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 14:24:27
Data point term sent to Coder	System	25 Mar 2021 14:23:33
Coding entries removed.	Lyly Dang (b) (4)	25 Mar 2021 14:22:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 11:45:37
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 11:45:37
Data point term sent to Coder	System	23 Mar 2021 19:43:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

Name of Medication

Audit	User	Time (GMT)
User entered 'potassium chloride'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 19:42:45

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:42**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'HYPOKalemia' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Mar 2021 14:22:47
User entered 'hyponatremia'	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:42**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered '20/100'	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'Other (OTHER)'	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'meq/me'	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'once (ONCE)'	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'Intravenous (INTRAVENOUS)'	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered '16 Jan 2021'	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:42**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:42**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered '16 Jan 2021'	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 19:42:45
	(b) (4)	

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User entered empty.	System	23 Mar 2021 19:42:45

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User entered empty.	System	23 Mar 2021 19:42:45

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:53:42

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:51
User entered empty.	System	23 Mar 2021 19:42:45

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:17:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:17:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 12:44:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 12:44:31
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
Data point term sent to Coder	System	25 Mar 2021 15:03:18
User entered 'Sodium chloride 3%'	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'No (N)'	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'Hyponatremia'	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered '100'	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:42**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'mL (mL)'	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered empty.	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'once (ONCE)'	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered empty.	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered empty.	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered '16 Jan 2021'	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered '0'	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'No (N)'	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered '16 Jan 2021'	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'No (N)'	Lyly Dang (b) (4)	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:53:42

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User entered empty.	System	25 Mar 2021 15:03:15

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User entered empty.	System	25 Mar 2021 15:03:15

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:42:53
User entered empty.	System	25 Mar 2021 15:03:15

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:11:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:11:47
Data point term sent to Coder	System	15 Apr 2021 19:23:38
Coding entries removed.	Angie Kean (b) (4) (b) (4)	15 Apr 2021 19:22:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: NICOTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 10:33:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 10:33:42
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	25 Mar 2021 15:21:51
Data point term sent to Coder	System	25 Mar 2021 15:21:47
User entered 'nicotine 21mg/24 hour patch'	Lyly Dang (b) (4) (b) (4)	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	25 Mar 2021 15:21:51
User entered 'No (N)'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Lyly Dang (b) (4)	26 Apr 2021 11:36:37 16 Apr 2021 14:22:42
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM). Signature has been broken.	Angie Kean (b) (4) Angie Kean (b) (4)	15 Apr 2021 19:23:07 15 Apr 2021 19:22:43
User entered 'nicotine addiction' reason for change: New Information	Angie Kean (b) (4)	15 Apr 2021 19:22:43
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Lyly Dang (b) (4)	07 Apr 2021 12:54:55 25 Mar 2021 15:21:51
User entered 'hyponatremia'	Lyly Dang (b) (4)	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	25 Mar 2021 15:21:51
User entered '1'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	25 Mar 2021 15:21:51
User entered 'Other (OTHER)'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'patch'	Lyly Dang (b) (4)	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'once daily (QD)'	Lyly Dang (b) (4)	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	25 Mar 2021 15:21:51
User entered empty.	Lyly Dang (b) (4) [REDACTED] [REDACTED]	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered 'Transdermal (TRANSDERMAL)'	Lyly Dang (b) (4)	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	25 Mar 2021 15:21:51
User entered empty.	Lyly Dang (b) (4) [REDACTED] [REDACTED]	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	25 Mar 2021 15:21:51
User entered '16 Jan 2021'	Lyly Dang (b) (4)	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	25 Mar 2021 15:21:51
User entered '0'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	25 Mar 2021 15:21:51
User entered 'Yes (Y)'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	25 Mar 2021 15:21:51
User entered empty.	Lyly Dang (b) (4) [REDACTED] [REDACTED]	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:53:42

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	25 Mar 2021 15:21:51
User entered 'No (N)'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	25 Mar 2021 15:21:39

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:53:42**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:21:39

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 15:21:39

**US3812062**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:53:42**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 15:21:39

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:53:42

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:01:02
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Signature has been broken.	Lyly Dang (b) (4)	25 Mar 2021 14:37:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Mar 2021 14:37:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User entered 'No (N)'	Karen Knapp (b) (4)	03 Sep 2020 12:39:50

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:53:42

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	26 Mar 2021 19:45:35
User entered '16 Jan 2021'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	25 Mar 2021 14:39:19

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:53:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	26 Mar 2021 19:45:35
User entered 'Chest x-ray'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	25 Mar 2021 14:39:19

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:51:23
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'WORSENING HYPONATREMIA clearly states con procedure was done. Thank you' (Site from DM).	Breanna Galibert (b) (4)	08 Apr 2021 15:05:41
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:06:58
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Adverse Event (AE)'	Lyly Dang (b) (4)	25 Mar 2021 14:39:19

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:53:42

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	26 Mar 2021 19:45:35
User entered empty.	Lyly Dang (b) (4) [REDACTED] [REDACTED]	25 Mar 2021 14:39:19

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:53:42

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:15
User closed query 'Per DM CLR: Please review the Date of this procedure, as it is out of the expected timeframe with AE# 3 (Fall, 14 JAN 2021- 14 JAN 2021). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:51:55
Query 'Per DM CLR: Please review the Date of this procedure, as it is out of the expected timeframe with AE# 3 (Fall, 14 JAN 2021- 14 JAN 2021). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'conprocedure withing timeframe for SAE associated with it hyponatremia' (Site from DM).	Anya Penly (b) (4) (b) (4)	06 Apr 2021 20:35:17
User opened query 'Per DM CLR: Please review the Date of this procedure, as it is out of the expected timeframe with AE# 3 (Fall, 14 JAN 2021- 14 JAN 2021). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 22:34:22
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '16 Jan 2021'	Lyly Dang (b) (4)	25 Mar 2021 14:41:23

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:53:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:15
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'CT head without contrast'	Lyly Dang (b) (4)	25 Mar 2021 14:41:23

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:15
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:52:54
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'WORSENING HYPONATREMIA clearly states con procedure was done. Thank you' (Site from DM).	Breanna Galibert (b) (4) (b) (4)	08 Apr 2021 15:06:08
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:06:42
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Adverse Event (AE)'	Lyly Dang (b) (4)	25 Mar 2021 14:41:23

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:53:42

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:15
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered empty.	Lyly Dang (b) (4)	25 Mar 2021 14:41:23

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:53:42

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:19
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '19 Jan 2021'	Lyly Dang (b) (4)	25 Mar 2021 14:43:02

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:53:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:19
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'US carotid doppler'	Lyly Dang (b) (4)	25 Mar 2021 14:43:02

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:19
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:54:33
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'WORSENING HYPONATREMIA clearly states con procedure was done. Thank you' (Site from DM).	Breanna Galibert (b) (4) (b) (4)	08 Apr 2021 15:06:15
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:07:10
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Adverse Event (AE)'	Lyly Dang (b) (4)	25 Mar 2021 14:43:02

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:53:42

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:19
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered empty.	Lyly Dang (b) (4)	25 Mar 2021 14:43:02

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:53:42

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:23
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '19 Jan 2021'	Lyly Dang (b) (4)	25 Mar 2021 14:43:51

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:53:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:23
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'ECHO'	Lyly Dang (b) (4)	25 Mar 2021 14:43:51

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:23
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:54:42
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'WORSENING HYPONATREMIA clearly states con procedure was done. Thank you' (Site from DM).	Breanna Galibert (b) (4)	08 Apr 2021 15:06:20
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:07:23
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Adverse Event (AE)'	Lyly Dang (b) (4)	25 Mar 2021 14:43:51

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:53:42

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:23
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered empty.	Lyly Dang (b) (4)	25 Mar 2021 14:43:51

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:53:42

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:26
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '16 Jan 2021'	Lyly Dang (b) (4)	25 Mar 2021 14:44:50

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:53:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:26
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'EKG 12-lead'	Lyly Dang (b) (4)	25 Mar 2021 14:44:50

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:26
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:54:48
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'WORSENING HYPONATREMIA clearly states con procedure was done. Thank you' (Site from DM).	Breanna Galibert (b) (4) (b) (4)	08 Apr 2021 15:06:26
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:07:33
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Adverse Event (AE)'	Lyly Dang (b) (4)	25 Mar 2021 14:44:50

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:53:42

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:26
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered empty.	Lyly Dang (b) (4)	25 Mar 2021 14:44:50

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:53:42

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:30
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '17 Jan 2021'	Lyly Dang (b) (4)	25 Mar 2021 14:57:06

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:53:42

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:30
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'EKG 12 lead'	Lyly Dang (b) (4)	25 Mar 2021 14:57:06

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:53:42

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:30
User closed query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:54:53
Query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'WORSENING HYPONATREMIA clearly states con procedure was done. Thank you' (Site from DM).	Breanna Galibert (b) (4)	08 Apr 2021 15:06:32
User opened query 'Per DM: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:07:44
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered 'Adverse Event (AE)'	Lyly Dang (b) (4)	25 Mar 2021 14:57:06

US3812062

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:53:42

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:30
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered empty.	Lyly Dang (b) (4)	25 Mar 2021 14:57:06

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'USA-US111-2021-MRNA-1273-P301000007'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'lauren'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Larkin'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'clement'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Wadsworth'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '711 Old Ballas Rd Suite 105'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'St Louis'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
User entered 'MO'	System	24 Mar 2021 18:30:11

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '63141'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:30:12
User entered 'US'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 18:48:26
User entered '6'	System	07 Apr 2021 18:23:31
User entered '5'	System	26 Mar 2021 18:12:25
User entered '4'	System	25 Mar 2021 13:21:42
User entered '3'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '2'	System	11 Feb 2021 16:30:31
User entered '1'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'USA-US111-2021-MRNA-1273-P301000007'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'lauren'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Larkin'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'clement'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Wadsworth'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '711 Old Ballas Rd Suite 105'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'St Louis'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
User entered 'MO'	System	24 Mar 2021 18:30:11

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '63141'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:30:12
User entered 'US'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 18:48:26
User entered '6'	System	07 Apr 2021 18:23:31
User entered '5'	System	26 Mar 2021 18:12:25
User entered '4'	System	25 Mar 2021 13:21:42
User entered '3'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '2'	System	11 Feb 2021 16:30:31
User entered '1'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:53:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User entered '20/Jan/2021 07:41'	(b) (4) System	20 Jan 2021 12:41:38

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:53:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:30:12
User entered 'I'	(b) (4), (b) (6)	20 Jan 2021 12:41:38

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'USA-US111-2021-MRNA-1273-P301000007'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'lauren'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Larkin'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'clement'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Wadsworth'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '711 Old Ballas Rd Suite 105'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'St Louis'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
User entered 'MO'	System	24 Mar 2021 18:30:11

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '63141'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:30:12
User entered 'US'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 18:48:26
User entered '6'	System	07 Apr 2021 18:23:31
User entered '5'	System	26 Mar 2021 18:12:25
User entered '4'	System	25 Mar 2021 13:21:42
User entered '3'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '2'	System	11 Feb 2021 16:30:31
User entered '1'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:53:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User entered '11/Feb/2021 11:30'	(b) (4) System	11 Feb 2021 16:30:31

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:53:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 16:30:31

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'USA-US111-2021-MRNA-1273-P301000007'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'lauren'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Larkin'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'clement'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Wadsworth'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '711 Old Ballas Rd Suite 105'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'St Louis'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
User entered 'MO'	System	24 Mar 2021 18:30:11

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '63141'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:30:12
User entered 'US'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 18:48:26
User entered '6'	System	07 Apr 2021 18:23:31
User entered '5'	System	26 Mar 2021 18:12:25
User entered '4'	System	25 Mar 2021 13:21:42
User entered '3'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '2'	System	11 Feb 2021 16:30:31
User entered '1'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:53:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '24/Mar/2021 14:30'	System	24 Mar 2021 18:30:11

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:53:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 18:30:11

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'USA-US111-2021-MRNA-1273-P301000007'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'lauren'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Larkin'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'clement'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Wadsworth'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '711 Old Ballas Rd Suite 105'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'St Louis'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
User entered 'MO'	System	24 Mar 2021 18:30:11

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '63141'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:30:12
User entered 'US'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 18:48:26
User entered '6'	System	07 Apr 2021 18:23:31
User entered '5'	System	26 Mar 2021 18:12:25
User entered '4'	System	25 Mar 2021 13:21:42
User entered '3'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '2'	System	11 Feb 2021 16:30:31
User entered '1'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:53:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '25/Mar/2021 06:21'	System	25 Mar 2021 13:21:42

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:53:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 13:21:42

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'USA-US111-2021-MRNA-1273-P301000007'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'lauren'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Larkin'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'clement'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Wadsworth'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '711 Old Ballas Rd Suite 105'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'St Louis'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
User entered 'MO'	System	24 Mar 2021 18:30:11

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '63141'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:30:12
User entered 'US'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 18:48:26
User entered '6'	System	07 Apr 2021 18:23:31
User entered '5'	System	26 Mar 2021 18:12:25
User entered '4'	System	25 Mar 2021 13:21:42
User entered '3'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '2'	System	11 Feb 2021 16:30:31
User entered '1'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:53:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
User entered '26/Mar/2021 14:12'	System	26 Mar 2021 18:12:25

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:53:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 18:23:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:25
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 18:12:25
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
User entered '0'	(b) (4), (b) (6)	25 Mar 2021 13:21:42

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'USA-US111-2021-MRNA-1273-P301000007'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'lauren'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Larkin'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'clement'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Wadsworth'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '711 Old Ballas Rd Suite 105'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'St Louis'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
User entered 'MO'	System	24 Mar 2021 18:30:11

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '63141'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:30:12
User entered 'US'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 18:48:26
User entered '6'	System	07 Apr 2021 18:23:31
User entered '5'	System	26 Mar 2021 18:12:25
User entered '4'	System	25 Mar 2021 13:21:42
User entered '3'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '2'	System	11 Feb 2021 16:30:31
User entered '1'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:53:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
User entered '07/Apr/2021 14:23'	System	07 Apr 2021 18:23:31

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:53:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 18:48:14
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 18:23:31

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'USA-US111-2021-MRNA-1273-P301000007'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Yes (Y)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'No (N)'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'lauren'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Larkin'	System	20 Jan 2021 12:41:19

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Folder: SAE USA-US111-2021-MRNA-1273-P301000007

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered 'clement'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'Wadsworth'	System	20 Jan 2021 12:41:19

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '711 Old Ballas Rd Suite 105'	System	20 Jan 2021 12:41:19

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Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered 'St Louis'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
User entered 'MO'	System	24 Mar 2021 18:30:11

US3812062

Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 09:53:42

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:45:35
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:12:17
Un-reviewed for Safety.	System	24 Mar 2021 18:30:11
Signature has been broken.	System	24 Mar 2021 18:30:11
User entered empty.	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 12:41:31
User entered '63141'	System	20 Jan 2021 12:41:19

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:30:12
User entered 'US'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:53:42**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	07 Apr 2021 18:48:26
User entered '6'	System	07 Apr 2021 18:23:31
User entered '5'	System	26 Mar 2021 18:12:25
User entered '4'	System	25 Mar 2021 13:21:42
User entered '3'	System	24 Mar 2021 18:30:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:37
	(b) (4)	
User entered '2'	System	11 Feb 2021 16:30:31
User entered '1'	System	20 Jan 2021 12:41:38

**US3812062**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 09:53:42**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
User entered '07/Apr/2021 14:48'	System	07 Apr 2021 18:48:26

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Folder: SAE USA-US111-2021-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:53:42

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:23:20
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 18:48:26